MEETING

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OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

ENVIRONMENTAL CONTAMINANT BIOMONITORING PROGRAM

SCIENTIFIC GUIDANCE PANEL

JOE SERNA JR., CAL/EPA HEADQUARTERS

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APPEARANCES

PANEL MEMBERS

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Dr. Marion Kavanaugh-Lynch

Dr. Ulricke Luderer

Dr. Thomas McKone

Dr. Gina Solomon

Dr. Michael P. Wilson

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Mr. Allan Hirsch, Chief Deputy Dirctor

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Ms. Carol Monahan-Cummings, Chief Counsel

Ms. Fran Kammerer, Staff Counsel

Dr. Gail Krowech, Staff Toxicologist

Dr. Rachel Roisman, Public Health Medical Officer, Safer Alternative Assessment and Biomonitoring Section

Dr. Lauren Zeise, Chief, Reproductive and Cancer Hazard Assessment Branch

APPEARANCES CONTINUED

DEPARTMENT OF PUBLIC HEALTH

Dr. Peter Flessel, Chief, Environmental Health Laboratory Branch

Ms. Diana Lee, Research Scientist

Dr. Michael Lipsett, Chief, Exposure Assessment Section

DEPARTMENT OF TOXIC SUBSTANCES CONTROL

Dr. Myrto Petreas, Chief, Environmental Chemistry Branch

ALSO PRESENT

Mr. Davis Baltz, Commonweal

Dr. Betsy Carlton, Rhodia Group(via webcast)

Mr. John Dunlap, Dunlap Group

Dr. Amy Kyle, University of California, Berkeley(via webcast)

Ms. Fabiola Lao, Brest Cancer Fund

Dr. Kathleen Plotzke, Dow Corning

Dr. Rebecca Sutton, Environmental Working Group(via webcast)

Mr. Karluss Thomas, Silicones Environmental, Health and Safety Council of North America

Ms. Rachel Washburn, University of California, San Francisco(via webcast)

Dr. Miglena Wilbur, Department of Pesticide Regulation(via webcast)

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PROCEEDINGS

CHAIRPERSON MORENO: Good morning, everyone. This is Ed Moreno. And I am reconvening the Biomonitoring Program meeting. And, again, I'd like to thank the Panel Members for attending today and Program staff and all the people from the public this morning who are attending.

It's my job to inform everyone about some of the logistics in terms of restrooms and emergency exits, but I have to admit I wasn't paying attention yesterday.

(Laughter.)

CHAIRPERSON MORENO: So, Joan, could you -- do you remember where everything is.

OEHHA DIRECTOR DENTON: I'll help you on that. The restrooms you can go to the left and there are restrooms on the left. You can go to the right to the end of the hall, women's on the left men's on the right.

So either direction you go.

If the emergency alarm should sound, we'll just go out the exit doors, make a right and go down the stairs out into the plaza.

CHAIRPERSON MORENO: Thank you.

All right. Our agenda today, Panel members have the information in the packets and we also have handouts of the slide presentations available. They've been provided to the Panel members and available to the public.

We're going to be covering several potential designated chemicals, presentations by the Program staff for consideration by the Panel, and also an update on additional potential designated chemicals for further discussion.

The goals for the meeting today are to, first of all, for the Panel to provide recommendations regarding designated chemicals. And we will also have an opportunity to ask questions after each presentation. And the public will also have an opportunity to make comments on the presentation of the groups of chemicals this morning.

After the public provides comment, I would like to bring it back to the Panel for any additional comments and discussion, because the public -- I'm sure the public will have some valuable information and opinion that the Panel should consider. The way we will handle public comment is that we will hear the presentation by the staff and the Panel will have discussion. And, at that point, we will then open up to the public. If you'd like to make a comment, we'd ask that you fill out the purple information cards and -- pink today, sorry. Pink. And if you're comfortable, include your name and we will collect those and ask you to come to the podium and share your comments to the Panel.

We also are -- this is also being viewed on webcast. And for those of you who are watching over the Internet, if you have comments you'd like to share, we will receive them and we will share them here at the meeting. You can Email them to biomonitoring@oehha.ca.gov. And, again, we will read those aloud. And if you're comfortable, include your name and we'll mention that as well.

I ask that during the public comment session that if you can, please keep your comments focused on the presentation topic. And if you can look through the agenda and you can see the list of chemicals that we will be discussing today, so if you could, hold your comment -- if you see that chemical listed for later presentation, if you could, hold your comments on those groups of chemicals for later, we'd appreciate that.

We're going to be taking three breaks today. We'll take a break mid-morning and then will be breaking for lunch and then we will -- after we resume, we'll be taking one more break in the afternoon.

We have -- the materials as I mentioned, each of the Panel members have the materials for today's discussion. The public is -- the materials are out in front -- outside where you check in for the public who are in attendance today here in Sacramento. And for those of

you who are watching on the webcast, you can access and view the documents on the website as well. And that's it.

So, at this point, I have the pleasure of introducing Sara Hoover. Sara is the Chief of the Safer Alternatives Assessment and Biomonitoring Section at OEHHA. She'll provide an overview of the process by which chemicals are designated for the California Environmental Contaminant Biomonitoring Program.

(Thereupon an overhead presentation was Presented as follows.)

MS. HOOVER: Thank you, Dr. Moreno.

Before I get started, I just wanted to explain the relatively new organization of the Biomonitoring Program in OEHHA. That happened in July, so we now have this new section that I'm the Chief of, the Safer Alternatives Assessment and Biomonitoring Section. And that's where the OEHHA part of the CECBP is housed. And Dr. Rachel Roisman in my section is OEHHA lead for the Program. And she'll be up after my slides.

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MS. HOOVER: So I just wanted to remind -- the Panel knows, I know, about designated chemicals. I'll remind the audience about what a designated chemical is. So this is just a quote from the law. A designated chemical is, "...known to or strongly suspected of

adversely impacting human health or development, based upon scientific, peer-reviewed animal, human or in vitro studies."

And the chemicals that are already designated include those chemicals in the CDC National Reports on Human Exposure to Environmental Chemicals. And the SGP may actually recommend additional designated chemicals. And that's, in part, what we're going to be looking at today.

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MS. HOOVER: This just provides a little of the context graphically that we were talking about in the meeting yesterday. So we have this current pool of designated chemicals that include the CDC chemicals, that can be added to based on certain criteria for designated chemicals that I'll go over in a second. Then from that pool of designated chemicals, priority chemicals can be chosen based on the criteria for priority chemicals. And then given feasibility and resources, chemicals that will actually be biomonitored will be chosen from the priority chemicals.

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MS. HOOVER: So this summarizes, again, directly from the law the criteria that the SGP is to use in recommending additional designated chemicals. And I'm

just going to highlight certain words in each of these bullets. And those highlighted words are actually what was focused on in the designated chemical documents that you received.

The first is exposure or potential exposure; the second is known or suspected health effects; the third is need to assess the efficacy of public health actions; the next is availability of a biomonitoring analytical method; availability of adequate biospecimen samples; and the incremental analytical cost. So these are the criteria the SGP should use in recommending additional designated chemicals.

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MS. HOOVER: So I just wanted to frame the agenda item for today before I hand it off to Dr. Roisman.

So the purpose of today's agenda item is to follow-up on the potential designated chemicals that the SGP identified at the June meeting. Those are listed here. Actually, six of these will have a brief presentation, panel discussion and public comment, followed by panel recommendations on designation. The Panel may also recommend to follow -- do some more follow-up on those chemicals, if you're not ready to make a decision on designation or not.

Then for two of these groups, plasticizers and

pesticides, there will be a brief update on that later this afternoon.

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MS. HOOVER: So now I'd like to hand it off to Dr. Rachel Roisman and she's going to go over the process that we undertook in preparing for this meeting.

DR. ROISMAN: Good morning. So the workgroup that was formed at the June SGP meeting has been meeting approximately monthly since then. We've had a total of five meetings. This workgroup has been coordinated by staff at OEHHA. The workgroup members include Dr. Luderer, Dr. McKone, Dr. Solomon, Dr. Wilson and then CECBP staff from OEHHA, CDPH and DTSC.

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DR. ROISMAN: So workgroup activities. The goal was to explore the potential designated chemical groups that were identified at the June SGP meeting. So the workgroup undertook these activities by gathering information on the chemicals and crafting these draft documents. The drafts were brought back to the workgroup for comment and revision and then sent to the wider biomonitoring group, which includes members of the three agencies and departments that are involved in the Program for further review. And then they were released to the public.

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DR. ROISMAN: The goal of these documents was to produce something concise that the Panel members could use to guide the discussion regarding chemical designation. The documents are not meant to be comprehensive literature reviews. They are based on a combination of select primary literature and secondary sources and also some consultation with experts on specific issues.

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DR. ROISMAN: Documents were produced on six potential designated chemicals or groups of chemicals, and these are the ones that are outlined on the agenda. And the way that the documents are structured follows the six criteria for chemical designation, which were explained by Sara, but generally again include exposure, potential exposure, the known or suspected health effects, the relevancy to assessing the efficacy of public health actions, and then laboratory considerations, including analytical method availability, biospecimen availability and incremental analytical costs.

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DR. ROISMAN: The outcome of the workgroup. No decisions were made at the workgroup regarding designation. The goal was to produce these documents, to bring them forward to this meeting, so that they could be

the basis of further discussion. And that's what we're going to be going over today. And the workgroup activities are concluded. And we thank the members of the workgroup for their participation and their assistance.

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DR. ROISMAN: And now I'd like to introduce Dr. Peter Flessel -- reintroduce Dr. Peter Flessel, who is going to be speaking on the first chemical group, which is diesel exhaust and vanadium.

(Thereupon an overhead presentation was Presented as follows.)

CHAIRPERSON MORENO: Thank you.

Dr. Flessel, Dr. Culver had a question.

PANEL MEMBER CULVER: Yeah, maybe it's nitpicking. Is diesel exhaust considered a chemical?

DR. FLESSEL: Diesel is a complex mixture of chemicals.

PANEL MEMBER CULVER: That's what I believe it to be. And does it come then under the classification of a designated chemical? I find great difficulty in categorizing it as such.

DR. FLESSEL: You take the words right of out of my mouth. You're way ahead of us.

(Laughter.)

DR. FLESSEL: I think it's a complicated issue

and that's really the first thing I wanted to say. So let's get right into that.

We bundled diesel exhaust and vanadium together because actually vanadium informs biomonitoring about diesel on the one hand, and also it has its own potential as a designated chemical because of its toxicity.

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DR. FLESSEL: Oh, it changed its mind since yesterday.

Okay. Good.

Right you are, diesel exhaust is a complex mixture. It's a mixture of hundreds of organic and inorganic chemicals in gas and particle phase. Among that mixture are more than 40 cancer-causing compounds, including the PAH that the CDC does monitor, and the nitro-PAH that CDC is working on, but does not yet include in their reports, the national reports on exposure.

We recognize that exposure to diesel is ubiquitous among Californians. We're all exposed to diesel to one level or another. And there are especially high community exposures in areas where there are transportation corridors and ports. Probably the highest exposures are in certain worker populations, but in an ambient setting, around freeway, intersections and ports.

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DR. FLESSEL: California recognizes diesel exhaust as a Toxic Air Contaminant since 2005, when the Air Board noted that particulate emissions from diesel-fueled engines are responsible for the majority of cancer risks attributable to air pollution.

That's a strong statement.

And it's a major contributor to premature death from cardiovascular and lung disease, asthma attacks and other respiratory effects, and accounts for thousands of hospital admissions annually in California.

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DR. FLESSEL: Additionally, a number of international and national and State organizations have designated diesel exhaust as a known or suspected carcinogen, probable -- beginning with the International Agency for Research on Cancer almost 20 years ago. Prop 65 has designated it. Similarly NIOSH, Office of Environmental Health Hazard Assessment, the National Toxicology Program, U.S. EPA.

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DR. FLESSEL: So it's a carcinogen.

We've presented three approaches to biomonitoring. So the issue, of course, is in a complex mixture like diesel, could you find some signature chemical or chemicals that might be reflective of diesel

exposure. Then by measuring these in people, could you then use these markers to assess your exposure and your ability to control exposures.

So there are three approaches. The first two are fairly straightforward. The first one is to look at particular Nitro-Polycyclic Aromatic Hydrocarbons. And the one in particular that has been the focus of diesel research for a long time, with regard to biomonitoring, is nitropyrene metabolites. Nitropyrene is enriched in diesel particles. It's not exclusively produced by diesel engines.

You can produce 1-nitropyrene in your fire place. You get it out of gasoline engines, but it's enriched in diesel particles. And the metabolites of 1-nitropyrene, hydroxy amino nitropyrene could be measured in urine. That's one approach.

A second approach, which is quite interesting but yet unproven, is to look for low molecular weight aromatic compounds that are both hydroxylated and nitrated, so so-called, hydroxylated nitroaromatic compounds. These compounds in chamber studies have been shown to be emitted in two to three order higher magnitude than from gasoline engines.

So diesel engines, because of the combustion chemistry in a diesel as compared with a gasoline engine,

produce 100 to 1,000 times more of these hydroxylated nitroaromatic compounds. The ones of particular interest are the low molecular weight aromatics like benzene and toluene, that 1 ring, and naphthalene, which is two rings. So the thought there is to measure urinary metabolites of hydroxylated nitro derivatives of these low molecular weight aromatics. So that's the second approach that we are presenting.

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DR. FLESSEL: The third one is more complicated and it's not one that is easy to explain or easy to get your hands around on the first try, but I'll do my best. So it's to take a number of markers, each of which may inform us about diesel exposure, and then try and aggregate that information to produce some sort of signal about the diesel exposure.

First of all, measure a PAH. Most of the PAHs correlate with one another. And the one that has been used as the kind of gold standard for PAH exposure is metabolite of pyrene 1-hydroxypyrene, which can be readily measured in urine. It's a marker for PAH. But, again, it's not diesel specific. You can find it every time you burn a barbecue or toast your bread or get your gasoline engine vehicle out there as well as your diesel car.

The second marker is urinary vanadium. Vanadium

is found in air from burning of diesel and other fossil fuels. But it's not diesel-specific, it's present in food.

And the third marker is total serum immunoglobulin E, IGE. Traffic pollution studies demonstrate that when you are exposed to traffic pollution, the IGE signal increases. But, again, it's more around traffic than it is diesel-specific.

So those were the three -- and I should not give the Program credit for this tandem approach. Actually, this came from a CDC -- a U.S. EPA scientist who's worked extensively on this whole issue.

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DR. FLESSEL: Jane Gallagher is her name, a very, very nice supportive individual. We got a lot of help in trying to pull this story together from technical experts all over the country. They all answer their phones. It's great. And when they hear we're from California and talking about biomonitoring, they want to chat, which was encouraging too.

So what about these three approaches from a laboratory perspective. Well, the nitro-PAH approach, the measurement of 1-nitropyrene metabolites in urine is the most substantial, in the sense that a method has been published. Workers up at Washington in collaboration with

some researchers in Japan have developed and published a method, a very excellent method, to measure these 1-nitropyrene metabolites in urine. The method was published a year or so ago. And the levels do correlate with the 1-nitropyrene in air.

The down side is that these levels are very low. The levels of 1-nitropyrene in air are low. The levels of the metabolites of 1-nitropyrene in urine are even lower, and it's a difficult method to do. Analytically, it would require a lot of effort and it would focus our resource activities really on that method.

The hydroxylated nitro-aromatic metabolites in urine is a very interesting one. The methods are available to measure these compounds in urine. But the fact of the matter is that the studies haven't been done to confirm their actual presence as metabolites in urine. There are folks at the Northern California Cancer Center working in collaboration with an investigator at the Battelle Labs, who are trying very hard to get the research dollars right now to make this critical test.

As far as the three marker or tandem marker approach, the methods for the 1-hydroxypyrene, the vanadium and the immunoglobulin E are all readily available.

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DR. FLESSEL: Now, let's turn briefly to vanadium for its own sake. Vanadium exposures occur as the result of the use of vanadium pentoxide in diesel engine catalysts. Although, those who have looked carefully at this understand that the future use of the catalyst is not so clear of the vanadium catalysts. Diesel and fossil fuels do contain vanadium. And you also release vanadium when petroleum is refined and processed.

We get vanadium in the diet, in the grain cereal that you had this morning, in the shell fish you might have had last night, in the mushrooms that you had on your salad yesterday and so one. But it's poorly absorbed. Nevertheless, dietary interference, in terms of a signal, comes, other than the air exposures.

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DR. FLESSEL: Vanadium pentoxide is a Prop 65 carcinogen. It's also a teratogen in rodents. How good is it as a marker of exposure and how well would it work in terms of public health actions? With regard to diesel exhaust, may be -- diesel exhaust on land, then think about ocean-going vessel emissions in port communities, also diesel. It could serve function there.

Not clear how sensitive it is. One sort of discouraging aspect is the fact that in studies down in Riverside indoor and outdoor levels varied. So you don't

quite know what to make of that.

On the other hand, there is a very interesting study published by the Air Board in 2006 about air levels in the south coast basin where the levels of vanadium did vary and the very highest levels were seen in West Long Beach around the port areas. So that suggests that it might be a marker for diesel exposures in relation to the vessel emissions.

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DR. FLESSEL: What about the availability of analytical methods?

The methods are available. We could do vanadium in urine or blood using the instrumentation that we have. People have used urine, whole blood serum and hair as a biospecimen. The incremental costs of adding vanadium to a metals screen are not insurmountable. It's a little bit tougher to do than most other metals, because there's an intrinsic interference that occurs in the process. A matrix -- a combination of matrix materials matches the molecular weight of the vanadium, but there are technical solutions that the manufacturer brings to the table on that when they sell you the instrument. We could solve that problem.

Now, when we talked to CDC about it, CDC is great. They do things that are easy, right. They do

things that they can really do high throughput on it. So vanadium was -- they discouraged us on vanadium because it's a little bit harder to do. And that's really the reason why they don't have it in their current arsenal.

But it's something that we could do. If it was something that was a high priority for California and informed us about diesel and also on the issue of vanadium exposure, it's something technically that we could do.

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DR. FLESSEL: So let me try and summarize the discussion, which has focused largely on diesel, but has also included the vanadium.

No question, diesel is a major public health concern for California. As I read the materials, I was impressed with this again. Diesel is really a big story. And Gina reminded us of that several times.

Approaches to biomonitoring for diesel:

One, the 1-nitropyrene metabolite approach is the sort of maybe the conservative, the straightforward way to go. It's not -- I think specific is too strong a word. It's relatively specific for diesel, but it's very hard. It definitely would take a lot of effort to do that one method.

The hydroxylated nitroaromatics, if I had to bet, that will be the most interesting possibility, but it's

not yet proven. And I hope that situation changes very soon. And then there's this tandem approach using PAH along with the vanadium and the serum immunoglobulin E. Each marker is non-specific in the sense that it's not just coming from diesel. It comes from a variety of sources, combustion sources as well as, in some cases, the diet.

But the thought is that maybe you could do some kind of pattern recognition to unravel this multiplicity of information. You'd have to gather information on the 1-hydroxypyrene, on the vanadium and the serum IGE and take that and do some kind of smart pattern recognition that Tom could tell us about. And then pull out a signal for diesel and use that as the metric for diesel exposure.

When I was thinking about that, I was thinking, gee, that would probably be a great Ph.D thesis for somebody. But it's not something that the Biomonitoring Program is well prepared to do. It certainly needs further development for application for us. But it was very interesting to hear from the EPA and Jane Gallagher about this approach. It does have a focus on traffic though. There's nothing more that I'd like to see than the better markers for traffic exposure. So that's where we are on the diesel vanadium story.

CHAIRPERSON MORENO: Dr. Flessel, thank you for

the presentation.

Yes, Carol.

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: Dr. Moreno, this is Carol Monahan-Cummings, counsel for the Panel. And I just wanted to address Dr. Culver's question about whether or not diesel exhaust or diesel could be considered a chemical in terms of the Biomonitoring Program.

In terms of looking at the definitions that are contained in the law, the word "chemical" is not defined. The designated chemicals are, but that has to do with where to locate those kinds of things. In general, for other programs, like Prop 65, we have considered that the word "chemical" to be broad enough to include chemical mixtures, which is what diesel would be -- or diesel exhaust. Other programs IARC, NTP, other groups also list and consider chemical mixtures under their programs.

Also, specific to this law, one of the things that it says is that, "This group can recommend that the Program designate substances." Okay, so that's even, in some ways, a little broader than a chemical.

So I think you're fine in terms of if you wanted to designate diesel exhaust, it would be nice if the definition was a little -- was there, but I don't think that there's an issue with that.

PANEL MEMBER CULVER: I certainly agree with you. And there are many mixtures that we are concerned with, principally those that come out of industry.

I, however, am concerned about choosing diesel exhaust or diesel emissions as a designated substance, in that it's fairly easy to measure it in the atmosphere and it's fairly easy to measure human exposure, go to elemental carbon particles as a measure of exposure. Why go to all of the trouble of trying to identify a biomarker for diesel, since it is so easy to identify as an exposure substance.

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: Yeah, I don't think that's a legal question.

DR. ZEISE: And I think that that's probably one for the Panel to discuss among themselves and give us recommendations.

PANEL MEMBER McKONE: I would sort of argue the other issue in spite -- and this is from someone who sort of works both sides of this. But it actually goes to the issue you brought up, which I think is very powerful, the triangulation or even having -- I've actually worked on a paper where we looked at biomonitoring by itself. And it has some value. But there's so much noise trying to invert back to where it came from, that a little bit of monitoring data is useful. But the same problem is if you

just have monitoring, it really doesn't tell you what's going -- you really need the biomonitoring to tell you what's in people.

But on this theme of like two and three is better than one, you know without getting into it, there's a lot of papers about two pieces of information certainly just exponentially increases the reliability for inferring or testing the inverse hypothesis about the source.

So, I mean, I think you said there's Ph.D. I think there's a very sophisticated treatment. But at a fairly simple level, you could then demonstrate the power of having two or three components to really narrow down the likelihood of what you're seeing. I think that's -- I really like that. And I'm not sure that I agree with you that it's -- I mean, there is a treatment of that that can be very complex. But there's also a first order of treatment that we probably could engage rather quickly.

DR. FLESSEL: I'm glad to hear that.

PANEL MEMBER McKONE: I had another comment, but it's on sort of a different issue. Should I just --

CHAIRPERSON MORENO: Go ahead.

PANEL MEMBER McKONE: One of the other things in terms of priority, I think this could be very useful for -- there's a lot of movement in the fuel composition area that's likely to take place over the next decade.

We're seeing -- I mean, I work a little bit with the Air Resources Board on looking at fuel additives. And there's a great deal of effort to make diesel cleaner. There's also biodiesel. There's renewable diesel. There's all these things happening. I think it would be quite important scientifically to be able to see what difference that makes, to have a way of monitoring the population when these changes happen to really see how it plays out, in terms of a fairly robust marker of what's impacting exposure and ultimately health.

I mean, again, it's back to the time discussion we had yesterday. This is really, I think, could be very important for both scientifically in the terms of health research, but also in terms of policy to really pose the question what difference is it making that we're doing this big market transition in terms of public health.

PANEL MEMBER CULVER: But I would like to go back to my question and see if there is a possibility of getting a clear answer. Why do biomonitoring on substances that exposure is so easy to measure?

DR. FLESSEL: Well, I guess my first reaction would be typically we're not able to do exposure measurements on lots of folks. And when you do the kinds of studies you're talking about, they're more limited and focused on a few subjects. Whereas, the biomonitoring

really gets to hopefully a larger population to finding out exactly what's inside them.

I haven't convinced you, I can tell.

PANEL MEMBER WILSON: I guess the way I see that, picking up on your point there, Peter, is that there are measures of exposure and then there are measures of exposure. And, you know, one of the things that we've worked on is characterizing the difference between near-field and far-field exposures, for example. And that there are often orders of magnitude differences even in fairly confined work places to volatile organic compounds for example. And so measures of exposure taken in the breathing zone turn out to be extraordinarily important vis-a-vis measures taken environmentally, you know, even 25 to 30 feet away, for example.

And so in this case, I think what we are talking about is a robust and even more robust measure of exposure that I think will add to our knowledge base much more than our environmental monitoring that we're doing for diesel in communities and so forth.

And I think -- you know, I think a point that Tom is making that, first, we have a major public health issue in California related to diesel. It makes sense for us to do whatever we can to try to improve our knowledge about both the hazard and the exposure to that mixture -- that

substance. And that the composition of the exposure is going to change over time and it makes sense for us to understand as much as we can about that as well.

So I guess my point is that we can do more to understand exposure and this is a way to do that and it's going to improve our knowledge base over time.

OEHHA DIRECTOR DENTON: I'd like to just address that as well. This program is the California Environmental Contaminant Biomonitoring Program. One of the key purposes of the Program is to be able to evaluate the effectiveness of regulatory programs on these contaminants. And I think as we go through this, we will find contaminants for which this is true, for which there is a wide array of air monitoring or the monitoring.

But it's the evaluation of the effectiveness of these regulatory programs which this Biomonitoring Program is designed to assist. That's a key element. So I don't think this is unique to diesel exhaust, but it's a key element within, you know, the chemicals that we're looking at.

CHAIRPERSON MORENO: We have two more -- at least two more Panel members I believe that want to add comments, Dr. Solomon and Dr. Luderer.

PANEL MEMBER LUDERER: Some of what I wanted to say, I think just is really to echo what some of the other

Panel members have been saying. I think it's important to realize that the ambient exposure monitoring that's currently being done really doesn't get us to the level of individual exposures. And I think that that is really what the biomonitoring can add. You know, some of the things that Mike has mentioned, I mean, we also know for example the distance living from a freeway interchange over the distance that's very short of 50 to 100 yards of the exposures to diesel exhaust dramatically decrease, and can -- and so measuring levels in individuals and then correlating that based on our information that we'll be gathering from our questionnaires about where these individuals may live or other possible sources of exposure, can really help us to get a handle on what the exposure levels are in individuals, and particularly in susceptible subgroups, for example, such as children and pregnant women.

I think another important issue, which Joan just brought up, is that this kind of biomonitoring could help us assess the efficacy of these public health actions that have already been ongoing for quite a number of years to try to reduce diesel exhaust, not only in terms of reformulating the fuels that Tom was talking about, but also reducing traffic, you know, efforts in the ports to have ships on electricity and not using fuel while they're

burning fuel while they're in ports, et cetera.

So I think that even though the three different approaches that you outlined, none of them is perfect or entirely specific for diesel, I think that attempting to biomonitor diesel could really be an important thing to do.

My last thing that was really more of a question related to these three different biomonitoring approaches, kind of more of a lab question, and that is within the CDC measurements. They're measuring polycyclic aromatic hydrocarbon metabolites and I was wondering whether the -- it sounded like from what you were saying that the 1-nitropyrene metabolites couldn't necessarily be bundled with those other polycyclic aromatic hydrocarbons, or could they?

DR. FLESSEL: That's correct.

PANEL MEMBER LUDERER: They couldn't be.

DR. FLESSEL: You definitely couldn't bundle them with the PAH measures.

PANEL MEMBER LUDERER: What about the hydroxylated nitroaromatics?

DR. FLESSEL: I don't know, but I suspect not. But the answer is I don't know.

CHAIRPERSON MORENO: Dr. Solomon.

PANEL MEMBER SOLOMON: I was just thinking back

to the process that the Committee initiated at its first meeting to solicit public input regarding what chemicals should be designated and the public meeting we had on that topic in Oakland last summer. And the chemicals that we're looking at today sort of all emerged from that process. And we really heard quite strongly from, you know, a great number of sectors, from the public and also from others sister agencies, that diesel exhaust is an environmental contaminant of major concern here in California, and of also major opportunity, because of the fairly, you know, strict regulatory measures that the Air Resources Board has been putting into effect.

And so it really, in some ways, is a perfect fit for the Biomonitoring Program for us to really try to sort of become -- be a part of that process and help to assess the efficacy of these regulations. Also help to, you know, sort of by tracking diesel markers over time, and also looking at, you know, sort of differences in exposure across the State and across occupational categories where possible, so that, you know, we would fulfill that other aspect of the Biomonitoring Program, which is to identify populations at risk.

My only reservation about including diesel is really about whether we would be able to pass the hurdle of identifying a biomonitoring method that is adequately

sensitive and specific, and so forth, because I really wasn't aware that there was any decent method in place or available. And so I really want to commend Peter for doing very diligent research, finding some of the -- you know, digging out experts from all around the country who are looking at this and identifying three very promising pathways, that I think could allow movement forward.

My recommendation, you know, if others in the Panel feel comfortable with this, might be to move forward to designate diesel exhaust as an environmental contaminant for biomonitoring, with the recognition that there is still quite a bit of work that needs to be done to figure out, you know, how to actually make this happen, and to then make a decision about whether it's appropriate for a priority listing, which, at this point, I'm not quite sure it is, because we don't know exactly what the best methods for biomonitoring will turn out to be.

But by designating diesel, we would be sending an important signal and also sort of helping to spur that additional, sort of, research work that needs to be done to prior -- to decide about the priority status.

CHAIRPERSON MORENO: Thank you. I know Dr. Wilson has another comment. I just wanted to make a comment that I think it's good that the Panel is asking these questions, because we need to make sure that we have

open discussion and that we're all understanding what it is that we're here to do. So I'm encouraged by this discussion.

I am also looking at listening to the presentation. And what I'm picking up on is that, I agree, there is a tremendous amount of interest in the ability of the Biomonitoring Program to include diesel exhaust. But that what we're hearing today is that there are promising pathways and there is evidence that there's -- we're hearing that there's emerging evidence and emerging methods down the road. And so that should be -- we should be optimistic with regards to our ability in the future to measure diesel exhaust.

Dr. Wilson.

PANEL MEMBER WILSON: I would concur with Dr. Solomon that it makes sense for us to proceed with designating diesel exhaust as such. And I guess -- and also, Peter, thank you for the work. It was, you know, just very well written, very clear and really lays out the subtleties of the issues and the uncertainties very clearly.

And so I guess two things. One is it seems that, and correct me if I'm wrong, that the hydroxylated nitroaromatics are the best bet, mainly because diesel engines emit two to three times, I guess, in orders of

magnitude, those substances relative to gasoline. Is that the primary reason?

DR. FLESSEL: That's the primary reason. The other part is that these compounds ought to be found unmodified very much in the urine. So hydroxylated nitroaromatics you ought to be able to pull them out of the urine fairly readily.

PANEL MEMBER WILSON: And I guess, second, that there are not a lot of other competing sources of exposure for those substances. I mean, I guess in terms of specificity, these are probably the most specific for diesel.

DR. FLESSEL: Because of this two- to three-fold differential, between diesel and gas in terms of the emissions, yes.

PANEL MEMBER WILSON: And yet, that still -- that remains largely unanswered with respect to, I guess, exposure.

DR. FLESSEL: It proved that these materials are found in human urine that has to be done.

PANEL MEMBER WILSON: Exactly. Okay. And then the second is that, as you said on the vanadium, the CDC contemplated biomonitoring for vanadium as did the Rocky Mountain Biomonitoring Consortium. And they both abandoned it for a concern around determining

its -- around other background -- determining background levels and other, I guess, competing sources of exposure, right, and a lack of specificity.

DR. FLESSEL: Well, I guess partly it's lack of specificity and partly it's a technical issue. It's a little bit harder to do than lead and other metals.

PANEL MEMBER WILSON: A little more difficult to do. So I guess, you know, the question that we face then is if it makes sense for us to begin building a database, you know, for example, on biomonitoring data on hydroxylated nitroaromatics as a potential marker of diesel exhaust exposure with the possibility that information and knowledge is going to advance over time, but that it makes sense for us to build that information base now.

Could you just comment on that?

DR. FLESSEL: Well, I can comment on that. It makes sense for us to keep very close track of the work that's going on on looking for these hydroxylated nitroaromatics in human urine. And if that breakthrough occurs, if that demonstration is made, then we need to follow that literature very closely. But right now it hasn't yet been done.

Asa, do you have a comment on that?

PANEL MEMBER BRADMAN: Well, not directly. I've

been talking with Bob Gunier about their effort to get that funded. I think they will get it funded. And I know Marcia Nishioka of Battelle is pretty confident that it can work. One concern I have a little bit is that you note that the compound is enriched at about 100 to 1,000 times higher than the gasoline. But I'm a little concerned or curious about the ratio of fuel use of diesel to gasoline. And if that -- if gasoline is used at much higher levels, would we lose some of that specificity?

DR. FLESSEL: In the fleet, you mean?

PANEL MEMBER BRADMAN: Yeah, in the fleet.

DR. FLESSEL: I guess it would.

PANEL MEMBER BRADMAN: Would we lose some of that specificity?

DR. FLESSEL: I think we'd have to.

PANEL MEMBER BRADMAN: Yeah. And I don't know what that ratio is. I don't know if, Tom, if you do, but it might become a measure of a mixture of diesel and gasoline exposure.

DR. FLESSEL: I would agree.

CHAIRPERSON MORENO: Any additional comments before we ask for public comment?

PANEL MEMBER McKONE: I can just comment very briefly. I haven't worked out the details, but what you would have to do is look at triplicate realizations and

look for like -- you would -- if you get three highs on three different measures, you know, your confidence is very high that that person is exposed to something different than the median. And I think some of this takes -- it will take some calibration and some learning. But, again, we're talking as though we only have one measure. And I would agree that it's probably nonspecific if you use vanadium by itself.

But vanadium combined with two other, not so specific things, but the -- what we have to look at is the triplet may be very specific and may very much narrow our confidence about whether we're seeing somebody exposed to gasoline and diesel. And that's an issue which we can't resolve here, but I think it's one, you know, intuitively I think there's some power in informatics theory to really resolve something like that.

DR. FLESSEL: Right. And I would just add, we could certainly substitute the hydroxylated nitroaromatics for the 1-hydroxypyrene in the tandem approach, if that's a stronger signal.

CHAIRPERSON MORENO: Dr. Solomon.

PANEL MEMBER SOLOMON: Just one quick thought on that, is that by designating some of these chemicals, I think that the Committee may be -- you know, I'm not sure that we're saying that we should be using, you know, the

scarce funds of -- the public funds of the Biomonitoring Program to pursue these yet. We're not calling them priority chemicals.

But I think one thing that this could do is send a signal to staff that, you know, these chemicals are very much fair game for finding grad students or, you know, extramural funding support to pursue sort of improving the methods and moving forward to try to take some leadership on these issues.

And that, to my mind, is one of the key roles of the subgroup of chemicals that we designate, that are not the CDC chemicals. That what we're trying to do is sort of -- we're short on money. We won't be able to biomonitor them all, but what we can do is sort of start that process of finding some funding support, some grad students getting the methods up and running. And then the ones that emerge from that process are ones that we may want to prioritize over time.

CHAIRPERSON MORENO: Thank you. I think that's a very good point. The clear mandate for this panel is to designate the chemicals and then make suggestions for prioritizing among the designated chemicals. But the statute also allows the Panel to make recommendations regarding the design and implementation. And I think with the great working relationship between Panel members and

staff there can be additional recommendations to provide guidance as to how we move forward with chemicals that are designated but not yet prioritized for various reasons.

All right. At this point, why don't we go ahead and -- I'm going to ask if there are any public comments. I see one, two. And whether there were any Emails from people watching on the webcast?

Okay. I'd like to invite Mr. Davis Baltz back to the podium.

Good morning.

MR. BALTZ: Davis Baltz with Commonweal. I want to, first of all, thank the Subcommittee for all their work, not only for this chemical group, but all the others that we'll hear about later. And I know you've got a very long agenda today, so I'm going to be very brief.

But I think in terms of sending a signal -- coming back to our conversation of yesterday of, you know, raising the profile of the Program among Californians, and in particular communities who stand to benefit, designating diesel would be sending an important signal. But if you don't designate it, I think that would also send an adverse signal. So I would support the recommendation that I think I'm hearing from several of you to go ahead and designate diesel. And we'll sort of put off for some time whether we can prioritize, and that

will be based on resources and so forth. But I think communities in California will welcome the designation of diesel. And that will enable those of us who work in the public interest to engage these communities and hopefully bring them to some subsequent meetings.

So thanks.

CHAIRPERSON MORENO: Thank you, Davis.

I didn't receive any other cards from the public who's present. So were there any Emails?

Can someone tell me if there were any Emails?

No Emails received.

Okay, so with that, thank you.

Panel members, any other discussion on diesel exhaust?

PANEL MEMBER WILSON: I have a question. And maybe this was -- I didn't catch your name, but you're taking Carol's place for the moment?

OEHHA STAFF COUNSEL KAMMERER: Fran.

PANEL MEMBER WILSON: So Fran, you got here just in time. Well, I guess the question is that last year the State of California passed a law pertaining to analytical methods.

PANEL MEMBER WILSON: And essentially it's been a little while since I've read the text, but essentially that would allow the State of California to require a

company to develop analytical methods for substances that are identified in environmental media or in human tissues or fluids.

And the relevance of that law has not, you know, come to this panel's attention, I guess, as yet, but it probably should. And I guess the question here is -- if that's something that would be helpful on this -- with respect to diesel exhaust, if there's a question about analytical methods as markers for diesel exhaust, for example, if that's a law that could be employed?

OEHHA STAFF COUNSEL KAMMERER: That's a good question and I'll have to get back to you on that one.

PANEL MEMBER WILSON: Okay. All right. Thank you.

I guess would it be possible to have something on that today?

OEHHA STAFF COUNSEL KAMMERER: Yes, definitely.

PANEL MEMBER WILSON: Okay, terrific. Thank you very much.

DR. ZEISE: Lauren Zeise with OEHHA. We can try to get back today?

OEHHA STAFF COUNSEL KAMMERER: Yes.

DR. ZEISE: But, in fact, this issue has come up in earlier meetings, and perhaps the Panel would like to hear a broader briefing of this issue and the law and the

extent --

PANEL MEMBER WILSON: If possible, that would be terrific.

DR. ZEISE: And so if we can't do it today, we would do it at a future meeting.

PANEL MEMBER WILSON: Okay. Thank you.

PANEL MEMBER McKONE: Can I ask a quick clarification?

So what we're really -- you're talking not only -- I mean, in the case of diesel, the law really applies to somebody making a chemical and then they should have the ability to detect that chemical. But what this brings up is if it's converted. So like dioxin, nobody makes dioxin. So if you make a product that converts through combustion to dioxin. So if you make plastic, the chlorinated plastic, that you burn it and it turns into dioxin. I mean, it does raise a very complex issue about how much you are obligated for the downstream transformation of the substance you make, in terms of monitoring. It's either degradation products or it's combustion products, right?

DR. ZEISE: Yes.

PANEL MEMBER McKONE: Yeah, I think this is more complicated than something we --

DR. ZEISE: So it's not a simple response. And

that's why I think perhaps we might find in trying to get you an answer, that we need a little bit more time to look into it.

CHAIRPERSON MORENO: Okay. Further discussion from the Panel?

All right. At this point, I'd like to then ask the Panel if there's a consensus on diesel exhaust as a designated chemical. And in that, if there is a suggestion, the consideration for vanadium.

Would anyone like to offer a --

PANEL MEMBER WILSON: Well, I would propose that we designate diesel exhaust as a designated chemical.

CHAIRPERSON MORENO: Okay. And with regard -- and vanadium with regards to diesel exhaust? How would you -- would you include that?

PANEL MEMBER McKONE: I would suggest we don't cut it off, but I think it has -- if it were done alone, it probably wouldn't make it. But the power of it in combination with other factors and the issue that -- I know it's been abandoned, but that doesn't mean it might not be very useful. It's just that the others who have done it haven't really had people like Peter who could really make it work. I think we should give them some opportunity.

So I think that one is a little -- I would

suggest we say keep moving ahead on vanadium and maybe check on it again in terms of a process.

CHAIRPERSON MORENO: Okay. Dr. McKone, I think that might be different than recommending vanadium, keeping an eye on it versus recommending it.

Yes, Dr. Zeise.

DR. ZEISE: One possibility is if you would like to include vanadium in the overall diesel exhaust recommendation, that's fine. We just basically followed the designation at the meeting in June by going through the individual eight areas that the Panel identified. So it's fine, at this point, if you say well, in including diesel exhaust, it would also be a good idea that you consider vanadium as part of that mixture.

PANEL MEMBER LUDERER: Yeah. And I think also that by designating diesel exhaust as a chemical mixture, that if, in the future, some yet undetermined but even better signature compounds for biomonitoring diesel exhaust were discovered, that that wouldn't -- you know, we would -- that could still be pursued. So by designating it as a mixture, it really includes all the components of that mixture. So I would also favor designating diesel exhaust.

CHAIRPERSON MORENO: All right.

PANEL MEMBER BRADMAN: I just had a procedural

question. Are we, like, voting now or are we --

(Laughter.)

CHAIRPERSON MORENO: We're looking for a consensus, at this point, after this presentation and discussion. So just getting some clarity from this panel what the recommendation is to the Program that the Program understands the recommendation and that it meets the legal requirement.

So what I'm hearing is that the Panel is recommending diesel exhaust be included on the designated list of chemicals for biomonitoring to include vanadium in that context?

PANEL MEMBER BRADMAN: And I would support that. I certainly would support listing diesel exhaust as a designated chemical.

CHAIRPERSON MORENO: Okay.

PANEL MEMBER WILSON: I guess the question here, Ed, just to get mundane about it, but I guess in terms of our decision-making process, if we're going to have a consensus process, we have to decide if there is -- if Panel members can block consensus or if -- and if that's the case, if it's more appropriate to have a Robert's Rules of Order approach. And I guess we haven't decided that as of yet.

CHAIRPERSON MORENO: We haven't. Well, maybe we

could check with Dr. Denton and counsel on that. Up to this point, the Panel hasn't followed those rules. Is there a recommendation?

OEHHA DIRECTOR DENTON: The panel is providing advice to us, and so it's not a formal, you know, formal action that you're taking. It's in the area of advice. I think that the Panel may want to clarify, you know, who recommends this and who believes this is a good idea. And if there are alternate opinions, then, you know, it would be useful to know that as well.

I don't know if you want to take a vote or you want to say if there are any objections or however you want to do it, but we don't have to have a formal voting process. Do you have anything to say, Fran?

OEHHA STAFF COUNSEL KAMMERER: Basically, in the regulations themselves, there's no specificity on how to proceed. So if the Panel would like to --

CHAIRPERSON MORENO: So the Panel could choose to take a vote and record those in favor and those that object to the recommendation?

OEHHA STAFF COUNSEL KAMMERER: That would probably be appropriate.

CHAIRPERSON MORENO: That's fine. Would that please the Panel?

PANEL MEMBER WILSON: I think it would be

appropriate actually and to call for the question and have a second and all in favor and so forth. I mean, I think in terms of providing advice and guidance, that gives a very clear direction from the Panel.

CHAIRPERSON MORENO: Okay. Well, if that pleases the Panel, then we're getting the nod that we can do this. So let's goes ahead and do that. Could you go ahead, Dr. Wilson, and restate your recommendation?

PANEL MEMBER WILSON: I would propose that the Panel designate diesel exhaust as a designated chemical mixture for purposes of the Biomonitoring Program.

OEHHA STAFF COUNSEL KAMMERER: If I may just make a point, the Panel is to recommend a chemical. They're not designating.

PANEL MEMBER WILSON: That's what I meant.

(Laughter.)

PANEL MEMBER WILSON: I'll restate it, that I would recommend -- I would propose that the Panel recommend that diesel exhaust be a designated chemical mixture for purposes of the Biomonitoring Program.

PANEL MEMBER SOLOMON: I have a clarifying question. And so are you recommending that vanadium be subsumed into the diesel exhaust biomarker category?

PANEL MEMBER WILSON: Yes.

PANEL MEMBER SOLOMON: Okay.

PANEL MEMBER McKONE: Can I word that in a way that instead of signaling out and trying to micromanage it, we say we designate diesel exhaust and encourage a focus on those components that are most useful in getting a reliable -- so that there's some flexibility. I fear that if we say vanadium, then in six months you find out it's worthless, right, and then you're basically stuck, because you would have to back out. I mean, we shouldn't be too specific.

PANEL MEMBER WILSON: I mean, I think --

PANEL MEMBER McKONE: And so if we state mixture and then give this guideline and focus on those components most useful to the mixture, so you don't have to do the whole mixture. We're not saying do the whole mixture and we're not saying do vanadium and 1-hydroxypyrene, but instead pull out the components. Is that too vague or is it something that we should do?

DR. ZEISE: Yeah, I mean, what you're basically indicating is that you're trying to designate diesel exhaust. And I think when we get more to thinking about priority chemicals for biomonitoring, we can then think about and discuss which components of that mixture might receive more weight in trying to figure out what would be best to biomonitor in Californians.

So I think it's fine to designate diesel exhaust

with an understanding that you're talking about that mixture.

OEHHA DIRECTOR DENTON: So, Lauren, the way you framed it, that the Panel is now taking an action to designate. Now, Fran has said that it's a recommendation to designate, so I think we're back on the recommendation of the Panel to designate in its advice mode, diesel exhaust and the appropriate components as designated chemicals.

DR. ZEISE: Yes.

CHAIRPERSON MORENO: And that recommendation from the Panel is to the Biomonitoring Program, is that correct? I just want to make sure that's clear. Who's actually receiving the recommendation?

DR. ALEXEEFF: This is George Alexeeff. In looking at the statute, I'd like to make a suggestion. We can all think about what's the best way of stating this. But I'm thinking that maybe the Panel should recommend that diesel exhaust be added to the list of designated chemicals, all right. And I would also add listing designated chemicals for inclusion in the Biomonitoring Program. Something, I would think, I like that.

CHAIRPERSON MORENO: Dr. Wilson, is that acceptable?

PANEL MEMBER WILSON: Yes. So let me see if I

can restate the proposal to recommend that diesel exhaust be added to the list of designated chemicals for inclusion in the Biomonitoring Program.

PANEL MEMBER SOLOMON: I second that.

CHAIRPERSON MORENO: Okay. So Panel members who are in favor of the recommendation, do we need to go ahead and have a roll call? Would someone like -- I can't see everyone. Could someone call and keep track.

Dr. Zeise, will you do that?

DR. ZEISE: So the Panel members in favor of the recommendation?

OEHHA DIRECTOR DENTON: I think Lauren we want you to take the roll. So name the individuals and then take a vote.

DR. ZEISE: Okay. All right.

Ulricke Luderer?

PANEL MEMBER LUDERER: Yes, I'm in favor of the recommendation.

PANEL MEMBER McKONE: I'm in favor.

DR. ZEISE: Dr. Culver?

PANEL MEMBER CULVER: I'm in favor.

CHAIRPERSON MORENO: I'm in favor.

DR. ZEISE: Dr. Culver, was that a statement in favor.

PANEL MEMBER CULVER: Yes.

CHAIRPERSON MORENO: I'm in favor.

PANEL MEMBER WILSON: In favor.

PANEL MEMBER BRADMAN: Yes.

PANEL MEMBER KAVANAUGH-LYNCH: Yes.

PANEL MEMBER SOLOMON: In favor.

DR. ZEISE: So we have a unanimous in favor.

CHAIRPERSON MORENO: All right. Well, thank you. That was great that the Panel has taken some action this morning. So that's great.

We're scheduled to -- I think we're on close -- yeah, we're on schedule to move onto the next presentation.

MS. HOOVER: Dr. Moreno, I just want to interrupt for one second. We have to just take care of one small admin thing and then we'll -- just loading something on the computer.

CHAIRPERSON MORENO: Okay. Then I'll take this, just a brief moment, to mention, which I forgot to mention this morning, that the Panel has nine members. And unfortunately Dr. Julia Quint couldn't make it today, so she's unavailable to attend.

Okay. At this time, I'd like to introduce Gail Krowech, who is with OEHHA, a staff member with OEHHA. Gail. And Gail will be presenting to the Panel information on brominated and chlorinated flame

retardants.

(Thereupon an overhead presentation was Presented as follows.)

DR. KROWECH: Yeah. This is going to follow up on the Panel's request that we look at flame retardants for the last meeting. And the workgroup talked about several ways of categorizing them and suggested that brominated and chlorinated organic chemical compounds used as flame retardants would encompass most of the flame retardants of greatest concern. And so that's why this is the title here. And it would obviously include PBDEs which are already designated.

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DR. KROWECH: There are several structures -- various structures of brominated and chlorinated flame retardants just to throw them out here, aliphatic, like the chlorinated paraffins, cycloaliphatic --

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DR. KROWECH: -- aromatic with one or two aromatic rings. And also organophosphate.

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DR. KROWECH: Flame retardants can be either additive or reactive. Additive flame retardants are incorporated but not chemically bound to the material. So over time they can be released.

Reactive flame retardants are chemically bound to material in the product and they won't be released. If, however, there's an unreacted flame retardant in the product, that can be released.

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DR. KROWECH: Brominated and chlorinated flame retardants are extensively used in the United States and in California. The uses include plastic housing for electrical and electronic equipment, printed circuit boards, foam insulation in construction materials, upholstered furniture, textiles and paints.

The current production import volume is not available. I've put on this slide volumes for 2002 just to sort of look at what we know now that's different. Tetrabromobisphenol-A, which is the most extensively used brominated flame retardant, 90 percent of its use is as a reactive flame retardant, and 10 percent is as an additive flame retardant in plastics. That 90 percent as a reactive flame retardant is in printed circuit boards. And that use probably will be decreasing as there are substitutes now on the market and they're starting to be used.

DecaBDE has been banned by the European Union and also in Washington State and Maine. And new substitutes are emerging on the market. PentaBDE has been phased out.

And there are new flame retardants taking its place. Also, tris dichloropropyl phosphate has since 2002, and I'll go into this a little bit later, has now more uses in furniture foam.

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DR. KROWECH: Chlorinated and brominated flame retardants have been found both in indoor and outdoor environments. They're persistent. They've been found in air, sediment and soil, sewage, sludge, streams, in the Great Lakes and in the San Francisco Bay. They've been found in fish, marine mammals and predatory bird eggs. And they have been found in house dust, in office dust and in indoor air.

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DR. KROWECH: Some brominated and chlorinated flame retardants have also been found in blood, in breast milk, in adipose tissue and in umbilical cord and/or umbilical cord blood.

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DR. KROWECH: California has its specific exposure concerns. Technical Bulletin 117, TB 117, requires that all upholstered furniture, manufactured or sold in California, must meet specified flammability standards. It has resulted in extensive use of chemical flame retardants in California. Prior to 2006, pentaBDE,

the commercial mixture, was the primary flame retardant in furniture foam.

Effective 2006, California banned both penta- and octa-BDE mixtures. And substitute flame retardants are emerging as a result.

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DR. KROWECH: This slide shows the major PBDE substitutes in furniture foam. The first one Firemaster 550 is a mixture that contains two brominated flame retardants.

And the second one, TDCPP is a chemical that had been used for -- as a flame retardant in furniture formed before PBDEs came on the market, and now is being reused again. It's structurally very similar to the brominated tris that had been used in children's sleepware in the seventies, which is banned. And actually this compound TDCPP was used for a short time in children's sleepware before it was withdrawn.

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DR. KROWECH: These are some of the known or suspected health effects of brominated and chlorinated flame retardants. They include cancer, developmental toxicity, endocrine disruption, neurotoxicity and immunotoxicity.

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DR. KROWECH: This slide is going to be hard to read, but it's specific about known or suspected health effects of a number of brominated and chlorinated flame retardants. The cancer column is if there is an identification that the chemical has caused cancer or caused cancer in animals, and it's considered as causing cancer or probable human carcinogen, it's listed here. And most of these are listed under Proposition 65 or the National Toxicology Program -- or identified by the National Toxicology Program. The tris dichloropropyl phosphate, which I mentioned before as a flame retardant in furniture foam, was identified by the U.S. Product Safety Commission as a probable human carcinogen based on animal studies.

There's one decaBDE is check marked in parentheses and that is because the National Toxicology Program found some evidence of carcinogenicity.

The other two columns are -- the check marks indicate findings of either developmental toxicity or endocrine disruption. And there's -- we didn't put NT as not tested, where we didn't find anything, because it was not an exhaustive literature search, and there may, in fact, be some studies.

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DR. KROWECH: There's also a concern about health

effects based on structural similarity to other known toxicants. The brominated phthalate that is in the Firemaster 550 is brominated DEHP, diethylhexyl phthalate, which is an endocrine disruptor. It's listed under Proposition 65 as known to cause cancer, developmental toxicity and male reproductive toxicity. And it's one of six phthalates that's banned in California and children's toys.

The chemical below it is a brominated ethylbenzene. And ethylbenzene is known to cause cancer under Proposition 65.

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DR. KROWECH: There's also concern of health effects based on common structural features between the brominated and chlorinated flame retardants and other known chemicals that have been shown to be -- to have various toxicity.

These two flame retardants here have a chlorinated norbornene ring. And other carcinogens and developmental toxicants also have this same chlorinated norbornene moiety.

They include the flame retardant chlorendic acid, the organochlorine pesticides dieldrin, chlordane heptachlor and endrin, which are all listed under Proposition 65 as known to cause cancer or developmental

toxicity or both. The organochlorine pesticide endosulfan also has this same chlorinated norbornene moiety and it's banned in the European Union.

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DR. KROWECH: With regard to the need to assess the efficacy of public health actions, there are significant concerns about persistence, bioaccumulation and known or suspected human health effects of brominated and chlorinated flame retardants.

Biomonitoring would assess the impact of the PBDE ban and determine whether PBDE substitutes are also accumulating. It would also determine whether other brominated and chlorinated flame retardants are accumulating and uncover environmental and human health concerns.

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DR. KROWECH: With regard to the availability of laboratory -- of analytical methods, methods are available for many brominated and chlorinated flame retardants or they are being developed. Brominated and chlorinated flame retardants can be detected in blood or urine. In some cases, large sample volumes would be required.

And in terms of the incremental analytical cost analyses can be bundled with other brominated or chlorinated flame retardants.

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DR. KROWECH: So in summary, brominated and chlorinated frame retardants are extensively used in California. They have been found in people and in the environment and have known or suspected health effects. Laboratory methods are available and are being developed for most compounds.

CHAIRPERSON MORENO: Thank you, Dr. Krowech for the presentation. Questions and discussion now from the Panel.

Start over here. Dr. McKone.

PANEL MEMBER McKONE: My knowledge, which isn't complete on these, is that we really don't know even though they're found in house dust in the indoor environment and they're found in food and fish and things. There hasn't been a good study that's really sorted out where they're coming from or their relationship, because I've seen some studies that suggest it's household and others say it's food. And it probably varies by compound, but were you aware of it in this work?

DR. KROWECH: I'm not aware. I know that the brominated flame retardants that are now used in furniture foam have already been found in indoor dust and -- the Firemaster 550 brominated compounds have already been found in indoor dust, so there would be some exposure that

way, and in sewage sludge. And whether any of that goes into agriculture, you know, I'm not sure.

PANEL MEMBER McKONE: They can get -- if they have any volatility, they'll get into the atmosphere and enter through food webs by a fairly complicated pathway.

DR. PETREAS: If I can add -- Myrto Petreas. It's mostly in the dust, especially for nonreactive chemicals. Because they're relatively new, they haven't been well blended into the environment to end up in the food chain. I think eventually they will become part of the diet, but it is mostly -- specifically indoor micro-environment exposure.

DR. LIPSETT: Yeah, if I could add to that briefly. This is Michael Lipsett.

There has been at least one study correlating indoor dust levels with levels in breast milk. And there's a recent paper by one of your colleagues, Bill Nazaroff, that shows that some of these -- a number of these are semi-volatiles. And they form organic films on surfaces in the indoors and will volatilize so people can also inhale them as well.

And there's a study that was recently published comparing California house dust levels of the penta mixtures with others areas. It was only in California that there were airborne levels that were detected, just

because our house dust levels are 7 to 10 times higher than anywhere else in the country.

PANEL MEMBER McKONE: Kind of just follow up on that. Is there a systematic study of their persistence in indoor and ambient environments. And the reason I raise this is, like if you use DDT in a household environment, it persists on any oily surface for a very long time. But we also know that eventually if you use in lots of houses, it starts -- I mean, it has enough vapor pressure to start migrating over large regions because it's so persistent. And that's -- we may not have seen that pattern even play out for these things, because we haven't had enough time. But it would require a systematic evaluation of their, you know, their reactivity in the environment.

DR. LIPSETT: There may be a number of routes though with it being in house dust that people can absorb it. One would be via inhalation. Another could be on the palmer -- on people's palms, for example. There is a recent study that Heather Stapleton did examining concentrations of BFRs on people's palms versus the dorsal surface of their hands. But the palmer surface being much higher, so you could easily, if you don't wash your hands thoroughly before preparing food, end up ingesting it as well.

So these different exposure routes are being

investigated, but we don't really have a definitive picture. But the most likely route of exposure is via indoor dust rather than being, you know, in the food chain. There have been some studies looking at potential dietary exposures as well in Scandinavia that suggests that fish contamination may be an important route for some people.

But in California, it's most likely going to be house dust. We're the primary receptors basically rather than having to go indirectly through the overall environment.

PANEL MEMBER McKONE: So I think it raises the point -- I mean, this is more of a comment. But I think it raises the point that the biomonitoring would have great value in sort of -- we haven't figured this out yet really, in terms of understanding pathways and the long-term playout with -- as the market -- again the market is changing so rapidly, it's unfortunate that we aren't out there already, you know, looking at what's happening and trying to understand the -- it's a dynamic system that's moving as we talk about it. And we could be looking at it. So I think it kind of argues for great value. Not that I'm recommending -- making a recommendation or anything yet.

CHAIRPERSON MORENO: Dr. Wilson.

PANEL MEMBER WILSON: Dr. Krowech, I want to thank you for a really thorough analysis here. I think it just was very well researched and a pleasure to read. And you gathered some really important data that I know is hard to get in many cases. And so I appreciate it.

And I guess I have a question and then a suggestion. And the first -- the question, first, is that I think you did a great job on identifying the substances -- these flame retardants that are both high-volume, and so exposure potential, as well as those that are emerging as a consequence of these various phaseouts.

And so I noticed that there was of the 13 that you evaluated, there were substitutes identified for penta, which is the Firemaster 550, and that there were two of those. One that appears to be, I guess, about four times more prevalent than one of the others. And then there was a substitute for deca. And so I'm wondering if there was -- so, the first is a question. If there's a substitute that we know about for octa, given its ban in California, that's the question.

And then the suggestion, perhaps for the purposes of the Panel in discussing these 13 substances, that it might make sense for us in our briefing document on page two, to number these substances from 1 to 13, because it's

just tricky -- I'm having -- the acronyms aren't listed on the chemical names here. And it's going to be tricky for us to use the chemical names. We'll be here till 4 o'clock I'm afraid.

So I would defer to the Chair on this, but I think for purposes of discussion, it might be easiest for us to number these and refer to them as numbers 1 through 13.

So I guess there's the proposal. So then the question is are there substitutes out there that we know about for octa?

DR. KROWECH: So octa was used in thermoplastics. And I'm assuming that some of these would also be used -- some of the ones in this document would be used as replacements for Octa. I don't know of specific other ones.

And just in terms of the substitutes for PBDE for penta, also the TDCPP is another one that's the chlorinated.

PANEL MEMBER WILSON: Right.

DR. KROWECH: So there are three.

PANEL MEMBER WILSON: TDCPP. Ed, do you want to respond to the, sort of, housekeeping question here then?

Thank you.

CHAIRPERSON MORENO: If I understand Dr. Wilson's

recommendation is that we just assign numbers to the list so that the Panel can refer to it quickly.

Is that going to be sufficient to -- will that be okay to keep the public informed as to what we're talking about, as long as the public has the list and can follow along?

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: Does the public have that list?

MS. HOOVER: Yeah, that's public.

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: Yeah, that's fine.

CHAIRPERSON MORENO: Okay, thank you.

PANEL MEMBER WILSON: So, for example, I think number 12 is TDCPP. And so -- and it might make sense for us to write in the acronyms. But in any case, let's number them 1 through 13, first.

CHAIRPERSON MORENO: Gina Solomon, you have a comment?

PANEL MEMBER SOLOMON: Yes. I also wanted to echo thanks to staff, to Dr. Krowech, for such a great write-up. And this was quite a challenge that the Panel threw at the staff at the last meeting, which was basically to say well, you know, we're concerned about the fact that California specifically, because of our most stringent flame retardant laws -- standards in the country

has much higher use of flame retardants. And that combined with the phaseout of a couple of the PBDEs, which are on the designated list, made us sort of throw out the question, what is there out there that we might want to be biomonitoring, that we might want to be concerned about. So it was a very sort of -- it was a broad question.

And staff really did hone in on this, you know, this group of chemicals that I think makes sense actually to think about as a group, eventhough there are some significant structural differences. And I think there's a number of reasons to think of them as a group.

One is, obviously, that they're all used essentially for the same thing. And they have certain structural similarities. Another is that they -- that we will easily hit this sort of -- a lot of slipperiness and difficulty figuring out which are used for what, like, you know, it's as -- I mean, as we've already seen that as some flame retardants get phased out for certain purposes, various other ones come in and then manufacturers move this way or that way, you know, to choose different ones of these for different purposes. And it's very hard to stay on top of that.

And so trying to -- and then the third reason is that for laboratory methodology reasons, and correct me if I'm wrong, Dr. Petreas, it appears that one can sort of

look at these from a laboratory perspective as a group. And in as much as that's possible, then moving them forward as a group would make some sense. So, you know, I guess -- I certainly would welcome any discussion about specific chemicals and think that makes sense, but I also think that if we do get bogged down in detailed discussions about each one of these, we could be here -- I mean, it could take up the rest of the day. So, you know, my suggestion might be to look at them, you know, as sort of as a general grouping of chemicals.

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: Excuse me. This is Carol Monahan-Cummings.

It was just brought to my attention that maybe the public, other than those on the webcast, don't have the list that you're talking about, so we're going to make a copy of them for the people that are here in the audience. So we need to make sure that they're clear on which chemicals we're actually talking about.

And also I'm going to offer a copy of the chemicals to the court reporter so it can be made part of the record of the proceedings, so that the record is clear.

PANEL MEMBER WILSON: Just following up, Gina. I think that's a good suggestion. And yet, I think Dr. Krowech has helped us identify the 13 that are listed here

for good reason, that they are -- they're both very high volume, up into the 500 million pounds per year, and those that are emerging as substitutes. And then she's listed an additional 16 that are, you know, presumably in commercial use. And I guess my suggestion -- or my proposal would be that we focus on the 13 that she has identified, at least as a first cut.

PANEL MEMBER SOLOMON: I agree. I think that makes sense.

DR. KROWECH: Can I respond to that?

CHAIRPERSON MORENO: Yes.

DR. KROWECH: Some of them are obviously very high-use chemicals. But there are others that I can't say are more used -- among these 13, I can't say they're more used than some of the other ones on the back list or that other ones that aren't on the list that we don't yet know about. So, you know, from my point of view, it might be very limiting, you know, if you should suggest just focusing only on the 13, because we don't know what's going to come around the corner in somebody's next publication.

PANEL MEMBER WILSON: Yeah. I guess, you know, we're running up against the need for a comprehensive chemicals policy in California. I mean, this is our dilemma. I guess the question, for purposes of the

lab, would be, you know, I guess sort of responding also to Gina's thought that, you know, to what extent is it reasonable to expand this initial list of 13 and include -- there's an additional 16 listed on the back of the briefing document. As we're looking at each of these, is there an incremental cost that's prohibitive or can these be grouped in ways that are efficient and so forth, cost effective? Can either of you respond to that?

DR. PETREAS: I can talk about a few of them. Some can be, let's say, easily added to the PBDE methodology. Some of them clearly not. For example, number 7 and number 11, very high volume, require their own analysis, their own instrumentation to start with. And I can't say about the rest. And my name is Myrto Petreas.

PANEL MEMBER WILSON: No, I know. Can you speak into the mic just a little. I didn't quite hear the last part.

DR. PETREAS: I said that number 7 and number 11 from the list are ones that I know do not conform with the current methodology. They require different instrumentation and different extraction. So it won't be an add-on. It will be a method on their own. Some others could be added to the PBDE methodology. And I can't tell about the rest. So we're going to need to be a little bit

more careful.

MS. HOOVER: Dr. Wilson.

PANEL MEMBER WILSON: Yes.

MS. HOOVER: This is Sara Hoover.

I just want to clarify something. And it's basically going along with what Dr. Solomon was talking about. The point of this document was to basically give example compounds for the class. The individual compounds are not necessarily chosen by any kind of priority. Obviously, we had some priority as we went through, but the back list there's some very high-volume on that as well.

And remember that, at this point, you're not making a decision about which to analyze. That's not what the decision is about. So the workgroup suggested and staff pursued this as a class. So that's what this document is about not the individual chemicals necessarily being singled out.

PANEL MEMBER WILSON: Right. Thank you for that clarification. And I guess a question for Carol would be originally we -- Carol, we had a -- during your absence -- a question about the applicability of AB 289 in requesting analytical testing methods for manufacturers of chemicals that are identified in various environmental media and human fluids and tissues.

And this would --

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: Could you tell me what that bill is. I'm not familiar with the number. Is it one of the Green Chemistry bills?

PANEL MEMBER WILSON: No. This was AB 289 in the previous legislative session.

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: Okay.

PANEL MEMBER WILSON: And it gives the State of California authority to request and receive analytical methods for detecting substances in environmental media and fluids and tissues, human fluids and tissues from producers.

And so this -- as compared to diesel exhaust, this would appear to me to be a place where that law would be very clearly applied with respect to specific chemical substances. And I guess this would be a question that I'd like to, you know, have addressed at some point.

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: We can -- Fran is looking at that now up there somewhere. And so we can touch base with you later. Hopefully, today. If not, subsequently about how those two interplay.

PANEL MEMBER WILSON: Okay.

CHAIRPERSON MORENO: Yes, Dr. Luderer.

PANEL MEMBER LUDERER: Yeah. I'd like to also support the idea that the original kind of idea of

grouping these various different flame retardants as the brominated and chlorinated flame retardants, because, I mean, from this really wonderful overview and presentation that we had, one of the things that I think is really -- comes out of this document is kind of how fluid the use of these different flame retardants really seems to be. And that in response to different market pressures and regulatory pressures, it seems that, at least the impression is that what I think that what happens is that manufacturers shift from moving one to the other with relative ease. And a flame retardant that may have been used, as you said, in the seventies and then declined in use is now increasing in use again.

And so I think that, in particular, because of the regulatory issues in California with TB 117 and possible additional regulations that might be on the horizon about flame retardant use that I think it's really important to keep this as a broad class, rather than focusing on certain particular flame retardants.

Another thing that really struck me and this is also kind of a comment in the document was the levels in house dust that we've already mentioned a little bit in the discussion. Some of them really are quite high for some of these flame retardants and this really raises a concern. I'm not -- for adults, exposure of course, but

also for children's exposure in particular with children playing in dust and putting things in their mouths all the time. I mean, that's a route of exposure that is of large concern and that I don't think we really have that much information about. And biomonitoring for some of these compounds could help us get a better handle on children's exposure, in particular, to some of these compounds.

DR. LIPSETT: Could I just make a comment in relation to what Dr. Luderer just said that you're probably aware that there is a very small scale biomonitoring study comparing children and their parents for levels of flame retardants. And in the children the median levels were about three times higher than in the moms. So it corresponds exactly to what you're talking about.

PANEL MEMBER BRADMAN: Just an additional comment related to that. In looking at some of the measurements that have come out of Richmond and Bolinas and we have a small study in Oakland and Salinas. If you were to do a exposure assessment based on default EPA assumptions for house dust for a small child, we're finding exposures that are five to eight times higher than the reference dose.

So these are really, I think, important public health issues. And it's going to be hard to sort out how to prioritize these different compounds, but I think

they're ones that we have to tackle and address very seriously.

CHAIRPERSON MORENO: All right. I'd like to ask for public comment at this time and then ask if there are any Emails commenting on this topic from people watching on the webcast.

Is it Fabiola Lao, did I say it right.

MS. LAO: Yes.

CHAIRPERSON MORENO: Thank you.

MS. LAO: Hi. Fabiola Lao with Breast Cancer Fund. We would encourage the Panel to highly recommend endocrine disruptors because of the evidence that these chemicals are linked to later life hormonally-related diseases, such as breast cancer. In addition, like it previously mentioned, we're seeing how these are negatively affecting children, especially at low-dose exposures. And additional information on the prevalence of these chemicals will be very critical to future research.

CHAIRPERSON MORENO: All right. Thank you.

Any comments before we move onto the next presenter from the Panel?

Okay. Also, Davis Baltz would like to speak again

MR. BALTZ: Davis Baltz with Commonweal.

The PBDEs, as was noted, are already designated as they're on the CDC list. So I would just encourage the Panel to make a recommendation for inclusion in the designated list. The class of CFRs, those that aren't on the CDC list already. You know, we pride ourselves in California on our environmental leadership. And one example of that would be the ban on penta and octa in 2006. I don't know how well it's being enforced. But as was noted in the presentation, we have this very problematic technical Bulletin 117. We're the only state in the nation that requires this flammability standard, which can only be met by the massive use of these chemicals into our furniture. And there's been no data that's been provided so far that this technical bulletin actually saves lives from fires.

So the presentation I think clearly pointed out that this class of chemicals meets all the criteria for designation. And, in particular, I'd just like to point out, although we haven't designed the intervention yet that might reduce exposure because of the technical bulletin and our ban on penta and octa, it would be very important to track how exposures to these chemicals are unfolding in California.

Thanks.

CHAIRPERSON MORENO: All right. Thank you.

We have two comments from the Email.

OEHHA DIRECTOR DENTON: Rebecca Sutton who is a senior scientist with the Environmental Working Group wrote an Email.

"The Environmental Working Group supports biomonitoring of brominated and chlorinated flame retardants as part of the California Environmental Contaminant Biomonitoring Program. The Environmental Working Group values the thoroughness of the list provided by OEHHA and asks OEHHA to consider medium- and long-chain chlorinated paraffins as potential testing targets as well.

"Manufacturers often developed proprietary blends of flame retardant compounds, so the Environmental Working Group suggests that they disclose to the State the chemicals they use -- and cross-checking common chemicals with the proposed biomonitoring list.

"So thank you for the opportunity to attend the meeting via webcast."

The other comment comes from Amy Kyle at UC Berkeley.

And she would like to "...submit the following comment for consideration by the Panel during an appropriate time on the agenda."

So I will go ahead -- it regards the persistence of flame retardants.

"Because of the grave concern about the potential for bioaccumulation and persistence of flame retardants, the likelihood that 'new' flame retardants will have the same sorts of characteristics as 'older' flame retardants, the evidence of exposure in California and the particular concern in California due to the State's flame retardant standards, which result in higher exposure than seen elsewhere," she suggests that the Panel make this recommendation as follows:

"The Panel recommends that the State include chlorinated and brominated flame retardants as chemicals eligible for consideration for biomonitoring.

"This then would allow sampling and analytical strategies be modified as

needed to reflect current science and changing patterns of use and so would be the most scientifically valid approach."

And her comment is "Cheers".

(Laughter.)

CHAIRPERSON MORENO: All right. Thank you. Thank you for all those comments. I'd like to hear back from the Panel.

PANEL MEMBER McKONE: With regard to the last comment from Dr. Kyle. Actually, I think that goes back to something we said probably in June that one of our intents was -- I mean, one of our concerns is we would be always biomonitoring for yesterday's problems. And that we wanted to make sure that we put in the system some flexibility so we could be looking at emerging products and not just flame retardants. I mean, this comes up with flame retardants -- comes up with fuels in combustion products as the fuel market changes. It comes up with consumer products. It's going to come up with plasticizers, pesticides.

There's always a changing market. So we have to keep one eye on what's happening now and one eye on a way to pick out what's going to happen. And I think we even said it in our summary report that we have to look at functions, and that was our breakdown. I think we've

somewhat done that. But we have to look at functions and biomonitoring the chemicals that cover a certain function, because once one goes away -- like flame retardants is a classic example, that that's a function that has to be maintained. And it's probably going to be a fairly persistent chemical. A nonpersistent flame retardant is not going to be effective. I can't quite imagine.

Now, pesticides you can get away with nonpersistent pesticides. But with flame retardants, it's looking like to maintain that function, it's going to have to be a chemical that has some characteristics that we want to be looking at. So I don't know if we can put that into our sort of recommendation to make sure that we're not just saying chlorinated, brominated and then make it sound like nothing beyond that, but make sure we're keeping an eye on this functional category of chemical.

CHAIRPERSON MORENO: Go ahead, Dr. Wilson and then Dr. Solomon.

PANEL MEMBER WILSON: Okay. Yeah, just to echo that, that our proposal, if we are to designate the brominated/chlorinated and I hear you saying, Tom, "other flame retardants", that that designation should be made as broadly as possible with the, you know, recognition that we are -- as the Panel has said, you know, we have these sort of regrettable substitutions in a very fluid market.

And I suspect that we are going to -- in the next, you know, fairly soon in California, have better information on the chemicals that are being introduced into the state, as my hope at least, as part of the Green Chemistry Initiative. And that I would hope that our proposal as a panel will allow the State to respond to that information as it emerges over, I think, you know in the next couple of -- year or two.

So I'm not going to make the proposal yet, but again just encouraging that we do it as broadly as possible.

CHAIRPERSON MORENO: Dr. Solomon and then Dr. Zeise has something to add.

PANEL MEMBER SOLOMON: Yes, I agree very much with at least proposing the brominated and chlorinated organic flame retardants as a broad category. I think that there's a little bit of a theme emerging here just coming over from -- spilling over from our discussion on diesel exhaust. That at the stage of designating chemicals, you know, it seems to me that what I'm hearing from the rest of the Panel, and I'm feeling myself, is that we want to designate fairly broadly and then allow, you know, some opportunity for the lab and, you know, staff to investigate further, so that at the prioritization stage, we may then hone in on, you know, a

smaller subset -- we will have to hone in on a smaller subset of priorities.

But that allowing maximum flexibility at the designated chemical stage does allow us to then do exactly what Dr. McKone said, which is, you know, try to stay on top of emerging issues as they arise and not just be sort of stuck monitoring for past chemicals.

CHAIRPERSON MORENO: Carol.

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: Excuse me. Carol Monahan-Cummings. I just wanted to suggest a couple things. One is that I understand why you want to go really broad and try to pick up things that you're not sure about yet.

But I wanted to remind you that this is an iterative process and you don't have to catch everything right now. It's not frozen. And so if it turns out that later there's some additional chemicals that need to be designated or prioritized, you'll be able to suggest that to the Program and that could be done later. So I don't think you need to try and make everything so broad that it will capture everything possible at this point.

A suggestion that I have in terms of how you might want to designate this group, if you choose to do so, is kind of if you base it on the title of the document that was presented to you, "The brominated and chlorinated

organic chemical compounds used as flame retardants," but then say also, "...including but not limited to those listed on page 2 and page 32 of the document." And then we would make sure that those two lists would be provided to the court reporter and be in the record.

So then you're kind of doing both things. You're saying here's the chemicals that we know we'd like to look at, if possible, but also it's broad enough to pick up other related types of chemicals used for flame retardants. Although, it wouldn't go outside the brominated/chlorinated organic compounds.

That's just a suggestion.

DR. ZEISE: And just to follow up, later on in the day, there is another agenda item around those flame retardants that aren't included in this class. So it's talking about the other chemicals that the workgroup actually discussed.

CHAIRPERSON MORENO: Okay. Further discussion or is this enough?

If not, is there a Panel member who wants to make a suggested recommendation?

PANEL MEMBER WILSON: Well, I'd be happy to jump in following up from that recommendation, that my proposal would be that we recommend that brominated and chlorinated organic compounds used as flame retardants, including but

not limited to those indicated on page 2 and page 32 of the December 4/5 briefing document, be added to the list of designated chemicals for inclusion in the Biomonitoring Program.

PANEL MEMBER LUDERER: I second that motion.

CHAIRPERSON MORENO: Okay. More discussion from the Panel members on what's been proposed?

If not, I would like to ask Program staff is that a clear recommendation?

Okay, I'm getting they're saying yes. Well, then, Dr. Zeise, could you call the roll.

DR. ZEISE: For those in favor, I'll just reflect that?

CHAIRPERSON MORENO: For those in favor?

DR. ZEISE: Dr. Luderer?

PANEL MEMBER LUDERER: In favor.

DR. ZEISE: Dr. McKone?

PANEL MEMBER McKONE: Yes.

DR. ZEISE: Dr. Culver?

PANEL MEMBER CULVER: Yes.

DR. ZEISE: Dr. Moreno?

CHAIRPERSON MORENO: Yes.

DR. ZEISE: Dr. Wilson?

PANEL MEMBER WILSON: Yes.

DR. ZEISE: Dr. Bradman?

PANEL MEMBER BRADMAN: Yes.

DR. ZEISE: Dr. Kavanaugh-Lynch?

PANEL MEMBER KAVANAUGH-LYNCH: Yes.

DR. ZEISE: And Dr. Solomon?

PANEL MEMBER SOLOMON: Yes.

DR. ZEISE: So it was unanimous.

CHAIRPERSON MORENO: Great. Thank you very much.

We're making great progress today.

Yes, so everyone deserves a break, a time out.

Okay, so is this a 10-minute break?

DR. ZEISE: Fifteen.

CHAIRPERSON MORENO: Fifteen. So I'm looking at the clock at the back. It's around 5 after 11, so the math would be 20 minutes -- 20 after. Twenty after we'll be back.

Thank you.

MS. HOOVER: Make it 25 after.

CHAIRPERSON MORENO: Twenty-five after.

Thanks.

(Laughter.)

(Thereupon a recess was taken.)

CHAIRPERSON MORENO: Okay. I'm calling the meeting back. Everyone back to your seats please and we'll get started.

We have just a couple of announcements.

Ms. Carol Monahan-Cummings.

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: Hi, this is Carol. I had a couple things. One, I just wanted to remind the group, once again, the Panel members, that during breaks and at lunch when we're having lunch today to make sure that you don't talk about the issues that are going to be decided by the Panel.

And I also have a little bit of information on Dr. Wilson's question on AB 289, which was a law that was passed in February of 2005. And it has to do with the State requesting information from chemical manufacturers and how that might interplay with the Program that we're talking about today.

A couple things. One is that certainly there is some room to use this law, I think, to collect information from chemical manufacturers about the products that they are producing. There is a process that's involved that's fairly extensive before you can ask a manufacturer directly for information, including looking in publicly available information -- or places so that they don't -- if the information is publicly available. There's no reason to ask the manufacturer for it. There's also some limits in terms of the manufacturers can designate certain information as trade secret, and so we would have to comply with that.

But there's a specific list of State agencies that are allowed to ask for information under the law. And that list does include OEHHA and CalEPA and pretty much all the boards and departments within CalEPA with the exception of the Department of Pesticide Regulation. And I think that's because they have their own statutes to allow them to ask for information.

And in terms of what kinds of information can be asked for that's relevant to this group, we could ask for analytical test methods. And that's defined in the statute and I think it's -- I could just read you the definition. I think it probably covers what you were asking about. It says, "Analytical test method means a procedure used to sample, prepare and analyze a specific matrix to determine the identity and concentration of a specified chemical, its metabolites and degradation products."

And that test method shall conform to the standards adopted by the National Environmental Laboratory Accreditation Conference. So it's, you know, a standardized test method.

And then the other things that can be asked for are bioconcentration factors, octanol-water partition coefficient. I have no idea what that is, but I'm sure you do.

(Laughter.)

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: So there is, you know, a number of different things that can be requested. But like I said, there is a process involved. My understanding is that under the law, CalEPA, the agency, has to coordinate these requests. And they don't have a specific process in place yet for coordinating them, but the Department of Toxics is already using this law to question information. And so we're going to touch base with them and see how that's working and maybe we could kind of piggy-back on what they're doing.

Does that help?

PANEL MEMBER WILSON: That helps. Thank you very much. Just a quick clarifying question on the trade secret matter. If that is -- does that allow information to be claimed as confidential that's requested by CalEPA or is it that CalEPA can access that information but can't make it accessible to the public?

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: Well, I think they still have to give the requesting agency the information, but it's protected from public release under, you know, the Public Records Act, for example, because it's a trade secret. But they would have to designate that and justify the asserting of that privilege. And, you know, that could be challenged at some point.

PANEL MEMBER WILSON: Can I ask one other, just a clarifying question.

I guess a follow-up question then is, in your view, does -- maybe for Dr. Flessel and Petreas, if that opinion has an impact on potential cost, you know, factors in thinking about development of analytical methods for the purposes of this discussion?

DR. FLESSEL: Certainly in principle it helps. In practice, in the long run, it would help. It's good to have methods available, that's for sure.

DR. PETREAS: Myrto Petreas. I agree with Peter. The question is, I think the law allows us to request information, but then someone has to digest the information, check it for completeness, accuracy and whether it can be directly applied to the question. We haven't done it yet, so we do not know.

PANEL MEMBER WILSON: Exactly. Thank you.

OEHHA DIRECTOR DENTON: Carol, part of the discussion was whether one -- whether we could request manufacturers to develop a test method. That doesn't sound like -- it sounds like there are already existing methods that we could request, is that right?

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: I don't think it's necessarily limited to things that have already been developed. I think we can ask for this information

to be provided. It doesn't say that it's already existing. But, you know, I have just really briefly looked at the law. I'd have to make sure. But the other thing I didn't mention is that the manufacturers are required to provide information within one year. Although, there isn't any enforcement provision within the law. So I suppose if they took longer than that, there's not a lot we could do about it. But one year gives me the impression that that could -- they're giving them that long because they would have to develop something potentially.

PANEL MEMBER BRADMAN: I have a question related to this. Does it require them to develop a method, for example, the technical product or provide some measure for the technical product or does it specify human tissues or environmental media?

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: Well, it seems to be limited to a specific matrix. But, you know, I'm not a scientist, so I'm not sure whether or not that's responsive.

PANEL MEMBER BRADMAN: So if the requesting agency specified a matrix, they would be required to develop a method for that matrix?

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: Right. And the definition of matrix is, "...including, but not

limited to water, air, soil, sediments, sludge, chemical waste, fish blood, adipose tissue, and urine.

PANEL MEMBER BRADMAN: Okay, that answers it.

Thanks.

CHAIRPERSON MORENO: All right. Well, thank you for following up on that and answering the Panel's questions. We also want to let the public know that the Program has made additional copies of the handouts on the topics that are being discussed today and those are again available just outside the doors.

All right. At this -- oh, I'm sorry, on the table in back there in the corner.

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: And that includes the longer briefing documents that we were discussing earlier.

CHAIRPERSON MORENO: All right. I want to introduce Dr. Rachel Roisman who is now going to present to the Panel on cyclosiloxanes.

(Thereupon an overhead presentation was Presented as follows.)

DR. ROISMAN: This presentation represents a brief overview of the summary document that was provided to Panel members and is available to the public on the back table.

And this represents a follow up on a Panel

request that we look at cyclosiloxanes. This was narrowed from the original topic that was brought in June of methylsiloxanes, based on the available information that was available suggesting that cyclosiloxanes in particular were the chemicals of most interest.

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DR. ROISMAN: So cyclosiloxanes are chemicals that consist of silicone and oxygen atoms that are singly bounded into a ring structure. And the ones that are -- three of the ones that are in most common usage are D4, D5 and D6 and the structures are outlined here.

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DR. ROISMAN: In terms of the criteria for inclusion on the designated lists. One of the first criteria is exposure or potential exposure. And these are chemicals that are widely used in a variety of industrial applications and in consumer products, including personal care products, cosmetics.

The annual U.S. import/production volume is -- the most recent data is 100 to 500 million pounds for D4 and D5 each individually and then a smaller number, 10 to 50 million pounds for D6. D5 also has been marketed as a safer alternative to perchloroethylene, which is used in dry-cleaning, which contributes to some extent to its higher import/production volume.

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DR. ROISMAN: So human exposure to these chemicals occur through two general mechanisms. One is the use of personal care and other consumer products. And the other, concern for human exposure is via environmental exposures.

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DR. ROISMAN: In terms of exposure in humans, there have been some estimates of daily exposure levels to individuals in the United States from the use of personal care products. And you can see a range from a milligram a day for D4 up to 200 plus milligrams or day for D5.

There are some indications of long half-lives in humans. There have been elevated levels found in women several years after the removal of silicone breast implants.

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DR. ROISMAN: The other potential area of exposure for humans is through the environment. Cyclosiloxanes have been found in air, soil, sediment, sludge and water. And most notably have been detected in fish and other aquatic organisms, suggesting their persistence.

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DR. ROISMAN: Known or suspected health effects

for D4. There's evidence of weak estrogenic effects and also benign uterine tumors have developed in rats.

For D5, there's evidence of uterine endometrial adenocarcinomas in female rats. Although the relevance to humans has been questioned. There's also evidence of the effects on the neurotransmitter dopamine and the hormone prolactin.

D6 has been shown to have effects on liver and thyroid enlargement and also reproductive effects in rats.

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DR. ROISMAN: In terms of assessing the efficacy of public health actions, as I mentioned before, cyclosiloxanes, in particular D5, has been offered as a substitute as a safer alternative for existing -- a variety of existing uses. And so we believe it's important to know if the substitutes that are being used are accumulating either in people or in the environment. And as referenced earlier, there are concerns regarding persistence in humans and in the environment, as well as evidence of toxicity of these compounds.

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DR. ROISMAN: Laboratory considerations. There are available analytical methods. There are two issues with the methods. First, is contamination from, you know, individuals handling the samples, as well as from the

laboratory equipment. And this would need to be worked out. And the other is a concern about evaporation. Biospecimen availability is fairly straightforward. They've been detected in plasma and blood as well as in a variety of other tissues.

In terms of the cost, the equipment needed for the detection is available in the laboratory, and cyclosiloxanes can be bundled with themselves, but they can't be bundled with other chemicals. And as I mentioned before, issues with contamination and evaporation will require refinement of methods.

CHAIRPERSON MORENO: Thank you, Dr. Roisman for the presentation.

Discussion by Panel members?

PANEL MEMBER SOLOMON: Just a clarification question. On slide 4 under exposure in humans that doses were milligrams per day not micrograms?

DR. ROISMAN: That's correct. That's exposure from use of personal care products.

PANEL MEMBER SOLOMON: So okay. That's pretty high. I'm used to seeing micrograms. So I was just wanting to be sure about that.

Thanks.

CHAIRPERSON MORENO: Dr. McKone.

PANEL MEMBER McKONE: Actually, my comment was

the same point. I'm trying to find the original reference to see whether they -- were you clear -- I can't remember whether they looked at the loading as the measure of exposure or the uptake and intake.

DR. ROISMAN: I believe it's loading, but I have the reference with me if you'd like to --

PANEL MEMBER McKONE: Okay, because I had the same reaction when I looked at those numbers. If you're taking -- you know, it's almost gram quantities of uptake or intake. That would be very large. But even -- so there's still the issue of how much uptake there is from the loading. It's a pretty high loading rate.

CHAIRPERSON MORENO: Dr. Luderer.

PANEL MEMBER LUDERER: The question that I had actually does also relate to that uptake of these compounds. I was noticing that, I think, for D4, D5 and D6 in the briefing document, there were some studies that you cited. One was an EPA document where there was a national survey of human adipose tissue that found all of these compounds in at least half or more of adipose tissue samples that were tested.

And then there was a later document, this 2003 document, by Flassbeck et al. where in the control women -- it was a study of women who had breast implants. But in the control women who didn't have breast implants,

it was mentioned that there weren't any cyclosiloxanes detected in adipose tissue. And I was wondering -- I mean, this made me think is there some trend in use over time that they were detected in adipose tissue in '82, but not in 2003 or is there -- were there different adipose tissues that are being looked at?

I mean, it seems that that's an important issue is, are these chemicals actually being taken up? And it looks like in most of the studies, they weren't detected in blood, they were only detected in adipose tissue. So maybe you can give some clarification.

DR. ROISMAN: I can give a little bit of clarification about that, but I think that there are also -- we also have here today some people who could perhaps offer a little bit more clarification than I can.

But I believe the 2001 and 2003 Flassbeck studies, which were the ones looking at women who had the breast implants, looked at both blood and adipose tissue. And it's true, there was this disparity. The numbers of people that they looked at in the range of three to five women in both the controls and the -- very small numbers. And I can't tell you, off the top of my head, what the limits of detection were or how their methods compared to what was done previously in the EPA study from, I think, 1982 or 1987.

So I don't know how the methods -- if there's a methodological explanation for that disparity or if it's, as you've suggested, more indicative of a change in use.

DR. PETREAS: If I can add something. Myrto Petreas. But the contamination issue, as was mentioned here, there's so much of them. They're so ubiquitous lately that they're everywhere. It's like they tried to do the phthalates in the past, you couldn't because there's so much phthalates in the environment, that's why we're going to the esters, to the metabolites. So maybe the metabolites would be the best solution here for the siloxanes, because we have done a little bit of work. And we've talked with other people who have done more work and it's easy, and we have detected siloxanes in sediments in wastes.

Not so easy to do it in low levels in blood because there's so much in the environment, in the lab, in the process of the chemist. So that's the difficulty that probably if we can find the metabolite would be the best solution.

PANEL MEMBER LUDERER: A follow up real quick. Are you suggesting that maybe in the earlier studies they were detecting environmental contamination and not necessarily --

DR. PETREAS: I can't tell, because I haven't

done it. Maybe. It's possible.

DR. ROISMAN: There's also one additional study that looked at -- which I can't remember if it's cited in the document, but a 2005 study where there were levels of cyclosiloxanes detected in breast milk, which is -- so in terms of evidence of these compounds in humans. There's the EPA study in adipose tissue. There are the Flassbeck 2001 and 2003 studies looking at the women who had breast implants. There's the study looking at their existence in breast milk. And then there's some modeling studies that looked at temporary storage in fat and bioaccumulation after -- but there's not a lot of evidence -- there's not a lot of studies looking at their persistence in humans.

PANEL MEMBER BRADMAN: Rachel, I have a quick question, too. On page three it talks about uses of D4 and fermentation, instant coffee production, diet, soft drinks. Could you clarify that, is that used in the creation of those projects? Is it an additive? Are they residues in food that are in the general population in the general food supply?

DR. ROISMAN: Yeah, I believe it's from the creation of the product, but I don't have the -- I couldn't tell you precisely. I'd have to get back to you on that.

PANEL MEMBER WILSON: I had a two-part question

for you. Just broadly, the first part -- the first part is if in evaluating this class of substances, if you, in your judgment -- did you feel there was sufficient, sort of a scale, I guess, from insufficient to sufficient information on hazard? So, you know, this looking, I guess, at toxicity bioaccumulation and persistence.

And if so, in your view, is the level of concern -- I'll give you sort of four possible levels of concern. One being scientific suspicion of risk. The second being reasonable grounds for concern. The third being balance of the evidence. And the fourth being clear evidence of cause and effect. So I'm asking for two judgments there.

DR. ROISMAN: And I guess also all within the confines of -- independent of the confines of the Biomonitoring Program and the, you know, criteria for designation, just as a separate issue?

PANEL MEMBER WILSON: Well, as a question of, you know, your -- in looking at this and sort of evaluating the literature to just give us a sense of the strength of the information and the strength and sort of a measure of the concern, based on the strength of the evidence.

DR. ROISMAN: Looking at the evidence, the things that concern me about these compounds are that they're very widely used. There's a lot of exposure. In terms

of -- I think there are a lot of questions that remain about toxicity of these compounds. And I think that I don't have all of the studies that we wish that we could have that could answer all those questions. But there are a number of studies that show a variety of toxic effects in different -- you know, from D4, D5, D6. So in more than one compound that makes some biological sense that are concerning.

I think it's concerning that they're showing up in the environment, in particular in fish, that demonstrates that they are persistent in the environment and I think that's concerning. And the other issue is that they are being increasingly used as, you know, replacement substitutes, and that makes me more concerned about them as well. And I don't remember the four choices for level of concern, but, I mean, I would put it -- I don't think it's a slam dunk. You know, I think there's still a lot of questions that remain in terms of toxicities and persistence. But I do think that there's certainly evidence that there's -- you know, there's certainly suspected health concerns. They're out there a lot. And, you know, we need more information about them. So one of those middle choices, I don't remember exactly which one it was.

PANEL MEMBER WILSON: Okay.

DR. ROISMAN: Does that answer your question?

PANEL MEMBER WILSON: Yeah, I guess if -- I know, I had to look them up, so I read them to you, so I'm cheating.

(Laughter.)

PANEL MEMBER WILSON: But I guess if on one end there's sort of suspicion of risk and on the other end is clear evidence of cause and effect, you know, sort of the latter would be lead, you know, sort of as a -- or mercury. You know there's clear evidence of cause and effect.

And perhaps on the scientific suspicion of risk might be some of the early findings on endocrine disrupting substances, for example. Along that continuum, where would this -- where would these substances lie with respect to, you know, your understanding of the literature?

DR. ROISMAN: Well, again, I mean, I should say this does not represent a comprehensive literature review. But based on the literature that I read, I think that there is evidence of hormonal effects. There is a concern about carcinogenicity. I know there's a question about whether the mode of action is relevant to humans, but that's still a question that's certainly -- I don't think that there is scientific consensus that these are nontoxic

substances, that there -- and OEHHA has said that, you know, officially that they cannot say that these substances -- that D5 in particular is nontoxic.

And so I think that, you know, in conjunction with evidence of them in fish and persisting in the environment as well as the fact that they're increasingly being used, you know, raises concern.

PANEL MEMBER WILSON: Okay. Thank you very much, Dr. Roisman.

CHAIRPERSON MORENO: Dr. Solomon has a question and then Dr. Denton.

PANEL MEMBER SOLOMON: Yeah, I just wanted to go back to the original rationale that I think this committee had to consider the siloxanes, which my recollection is that we -- that the discussion had to do with the phaseout of perchloroethylene for dry-cleaning, which is occurring, I can't remember exactly, by what date, but is mandated by the Air Resources Board. And so the Panel wanted to know about what's replacing perchloroethylene and that's sort of what got us to the cyclosiloxanes.

And so, you know, my question, I guess, is, you know, whether there's any information out there about the extent to which D5 is coming into California and is -- and, you know, whether there's any information out there as to whether, you know, what degree exposures

through dry-cleaning use might, you know, be significant contributors or even, you know, somewhat potentially significant contributors to human exposure.

I haven't seen any such information. If so, then, you know, obviously that could be in and of itself a rationale to collect it. But I was curious if there is anything, because I just figure you've looked into it.

DR. ROISMAN: I'm not aware of that. But I, in no way, think that that means that it doesn't exist. I'm just -- I don't have specific California data related to the dry-cleaning issue.

CHAIRPERSON MORENO: All right. I think, at this point, I'd like to ask for public comment on this topic. And do we have any requests to speak and were there any comments to be shared from Email?

All right. I have two requests. The first request is by Karluss Thomas.

And then we have one speaker following Mr. Thomas and then we have one Email that was sent in.

MR. THOMAS: Good morning. My name is Karluss Thomas. I'm the executive director of the Silicones Environmental Health and Safety Council of North America. We're a trade association that represents the North American manufacturers and importers of silicone materials.

First, I'd like to thank the Panel for the opportunity to come here and provide comments on the Biomonitoring Program. And also I'd like to point out that SEHSC does have a good history of working collaboratively with OEHHA. We have provided data to support ongoing problems in the past and look forward to continuing that in the future.

I do want to point out a couple of things about the potential inclusion of the cyclosiloxanes in the Biomonitoring Program. As was stated earlier by one of the previous Panel members, we don't believe that would be appropriate, given the publicly available information. I mean, in particular, with regard to previously published biomonitoring studies, including those in the background information provided by the Panel, do not seem to show any of these materials in blood or plasma from exposure to individuals associated with consumer products.

In addition, we also believe that the publicly available information data that's been developed to characterize the metabolic disposition of these materials, PBPK modeling in particular, do not suggest that these materials would be present in blood or plasma.

So I'm going to invite my colleague, Dr. Kathy Plotzke, who is one of our technical experts, can talk a lot more in detail about some of those specific items.

Thank you.

DR. PLOTZKE: Okay. What I thought might be helpful -- and as Karluss said, I'm Kathy Plotzke. I'm here on behalf of the Silicones Environmental Health and Safety Council. And I'm one of the key scientists that have been really studying these cyclosiloxanes on both the health and the environmental side.

What I thought I would do is, as requested earlier, go by the various slides that were reviewed on these materials and address questions and comments that I had, as well as I heard from the Panel.

So I would start with really the slide that was number four, looking at exposure in humans. And I think Karluss already made one of those points, as well as a number of the Panel members even pointed out and asked those questions, about some of the discrepancies about what's been reported in the literature on the finding of these materials in humans.

In particular, the citation of the long half-lives comes from some very old breast implant literature that has been out there for some time.

One, the first and most important point to emphasize is that they were not found in the controls. So I think that is a good question, why are we seeing differences there where we have control population. We're

assuming those individuals would have been using consumer products, personal care products, that contain these materials. And yet you did not find the presence of either SI or cyclosiloxane in those control individuals.

And then the second point on that is the indication of the half-lives in humans being long. I want to point out that that's associated with some very early work that was done on the breast implant research looking at total SI content, so total silicone content, not cyclosiloxanes.

And in even more recent work that was just cited here today and is in your overview where they've looked at the specific materials, the cyclosiloxanes, they clearly indicate once again, they're not found in the control women. And, again, presumably in 2003, these women were being exposed to consumer products containing these materials.

And two, that the total content of cyclosiloxanes in total SI from those older studies were very small. So the long half-lives refer to their -- refers to total SI content and are not appropriate for looking at the half-lives of the cyclosiloxanes.

And then really the third point on that, that I think is very important, is to look at more recent data that has been developed and generated on these materials

looking at the kinetics, as Karluss indicated, not only actual kinetic data, but kinetic modeling that has been done looking at the very specific behavior of the cyclosiloxanes by the appropriate routes of exposure that consumers are exposed to today. And that is through the dermal exposure and the inhalation exposure.

And one example I'll cite is work that was sponsored by the silicone industry at the University of Rochester where they actually used human volunteers to look at dermal absorption of D4 and D5, following even an exaggerated exposure of one gram exposure to the volunteers.

Another key point, again, to point out is that there was no detection of the test materials prior to the exposure. So they did a baseline. They did not detect the test materials that they were exposing the volunteers to.

And then following exposure, they did detect levels of these materials within the blood, but those concentrations peaked at one hour and there was a rapid removal of those materials from the blood and plasma.

The half-life of these materials in humans is very short. And you will see a peak immediately after exposure, but then they will disappear from the blood and that is based on their physical properties. They are

poorly soluble in blood and they do not like to remain in blood and they volatilize very easily through exhalation in the air.

This is particularly important for a dermal exposure. If you look at how dermal exposure occurs and how materials cross into the system in circulation, they go into the capillaries under the skin. The first area that they go to are your lungs. And because of the chemical physical properties of these materials and their partition coefficients from blood to air, they are rapidly removed into the air. So they are breathed out before they go to any further stomach exposure.

I want to come back now to answer a couple of the questions about some of the disparity of the literature reports. The work that was done back in the 1980s by EPA looking at fat concentrations of these materials. First of all, they did not look at concentration, so there was no indication of detection limits. It was only an identification and that was done by doing selective ion monitoring. And so there is an assumption that ions that they were monitoring were associated with these materials. But there's no direct proof that it was these cyclic materials that they were detecting and there were no concentrations reported.

In addition, what we can't rule out is the

contamination issue. And we did talk about that earlier as far as these materials are used, not only in a lot of consumer products, but they were also used in very common equipment found in all analytical laboratories. The septum on the GC, the column that you use to separate the materials to analyze, you will find these materials.

So it is very critical to ensure that you are not just dealing with background levels of these materials. And I think that is a good explanation for a lot of disparity that we're currently seeing in the literature.

The other one was around the breast milk samples, where these were reported to be found in breast milk by Sweden. We actually have looked very carefully at that methodology and those samples were not collected for the intention of analyzing cyclosiloxanes. And looking at how they were handled, it's very unlikely that what they reported were truly cyclosiloxanes. The handling of the materials would not be consistent with finding those materials in the breast milk.

Back to the metabolite question. We do know quite a bit about the metabolites of these materials and how these materials break down in the human body. The metabolites -- these materials are metabolized to very polar materials and are excreted in the urine. So they immediately leave the body. They don't want to stay in

the body. They'll be excreted in the urine.

The next slide I wanted to go to was the persistence in the environment. And I think that we've already talked about the use of these materials and that they are found in consumer and personal care products. And it is consistent that you would then find them in the environment.

However, the silicone industry has, underway, a robust research and monitoring program on the environmental fate and effects of these materials. That has been under way since about 2003. We have been working in partnership with UK Environment Agency, the European Commission and Environment Canada on various aspects of this research program.

One thing that everyone has acknowledged is the challenge of analyzing for these materials in various matrices. And, in fact, we have a program under way that's an inter-laboratory comparison amongst the industry labs, the Norwegian labs, Environment Canada to look at how do we better analyze for these materials, because of those contamination issues.

The other aspect to point out is that recently this year, in March, the UK Environment Agency, as well as the European Commission, made a decision to delay any further assessment around the persistence and

bioaccumulation of these materials until this research was completed.

And the reason for that is that there are serious questions to date around the data that has been generated and published, as to whether or not these materials truly are persistent and bioaccumulative in the environment.

A couple of examples in support of those questions are recent work that the silicone industry has been doing. One, looking at the persistence and the degradation of these materials. And what we have demonstrated and what you will find in the peer-reviewed literature is that these materials do degrade in the atmosphere. They degrade in soil. They degrade in water. And they also degrade in sediment. Recent studies on sediment are under way. We've supplied the preliminary results to Environment Canada and to the UK Environment Agency on D4 showing that it's degrading in sediment.

So the other aspect is the bioaccumulation component. And another recent study that's been completed and supplied to both Environment Canada and the UK Environment Agency is specifically looking at bioaccumulation up the food web. I've heard that question here today, and that is a concern. We do want to know whether or not these materials actually accumulate up the food web and can lead to significant exposures to humans.

We've actually conducted a food web exposure study in Lake Pepin in Minnesota, so collecting the various orders of the food web, and looked at the concentrations in that food web. And what this study clearly shows, these materials do not bio-magnify. In fact, they biodilute as you go up the food chain into the higher order of the food chain. So what humans will be exposed to is much lower than what you see entering the environment.

So those are just two examples around the persistence, and I'd say the persistence and bioaccumulation questions in the environment.

The next Slide, on Slide 6, the known or suspected health effects. And I think the question that was asked was probably the key question about the suspicion of risk versus the clear evidence of cause and effect. And it's clearly, and I even highlighted, suspected health effects versus the clear evidence of cause and effect. There is no clear evidence of cause and effect of health effects in humans with these materials. These materials have been used safely for over 40 years.

In addition, the silicone industry has an extensive data set, safety data set, looking at the health and also the environmental aspects in understanding the behavior of these materials in the mammalian system in

particular.

And even though we may disagree on some of the specifics that's cited on this slide, I think the most important point is that if you look at the extensive data set that's been generated, and that's short-term, medium-term, all the way out to long-term studies, reproductive, immunological, neurological studies, this is the summary or potential summary of some of the findings that you might see with these materials. And I think if you look at that, and then ask the next question, one, is the relevance of some of these findings to humans, the silicone industry has already committed and conducted work understanding the relevance of some of these findings to humans. In addition, then going on to conduct a very thorough exposure assessment, looking at, not only the environmental exposures but the consumer's exposures, which includes dry-cleaning, which was the question earlier and looking at exposure versus risk.

And not only has the silicone industry done it, but we've also provided that to Health Canada and Health Canada has conducted their own risk assessment on these materials. And the UK has also done it looking at the environmental exposures. Both agencies have stated there is no risk to human health from exposures to these materials with the safety data set that's available.

On the next slide, Slide 7, the need to assess the efficacy of public health actions. The silicone industry agrees with the importance to understand accumulation or the potential for accumulation of substitutes or any new chemicals coming into the environment in people.

And we believe that that is what we have done and studied in our program that we have put together on these materials over the last ten years, understanding both the health and the environmental effects of these materials.

This robust data set not only includes questions around how do you develop methods from an analytical perspective in the various matrices -- we've had to do that in order to study the fate and behavior of these materials -- but also a robust kinetic data set.

And I gave an example earlier of at least one of those studies that is available on actual human dermal exposure. And I think if you look at the full data set that's available, all the animal data set, the human data set that's available, as well as the physiological-based pharmacokinetics modeling that's been conducted to look at various exposure scenarios, what that demonstrates is that these materials do not accumulate in humans and that they are rapidly removed from humans following initial exposure.

And I think that combined with the understanding of the exposure and looking at risk that it clearly demonstrates that there is no human health risk to these exposures, and that there are serious questions around the environmental persistence and bioaccumulation. And a program is underway to be completed by 2009 to answer any remaining questions about these materials' behavior in the environment.

So hopefully I've answered some of the questions that were asked. I tried to capture them.

CHAIRPERSON MORENO: Thank you very much.

We have a couple of Emails. But before we get to that, I would like to bring it back to the Panel with additional questions before public comment.

PANEL MEMBER CULVER: Thank you very much for that presentation. I hope that the data you presented or summarized could be made available to the Panel.

In view of the findings from your studies, would you have any concern for siloxane being a substance that the Biomonitoring Program would look at?

DR. PLOTZKE: Well, I think the question would be is this really a priority to look at, given the data set that we just talked about. And we can make that data set available. There's actually already quite a bit of it out there in the public literature. All of the mammalian,

including the human kinetics, is published in peer-reviewed literature. And the environmental work is being published as we're generating it, so we can make it available. And we've made it available to Environment Canada, the UK Environment Agency and the European Commission as we've been working with them.

So, definitely, we can make that available. But I guess the question is given the data set that is available and the questions around whether or not you would truly find these materials in plasma and blood if you did monitoring, is it really a priority?

DR. ROISMAN: If I could just --

CHAIRPERSON MORENO: Dr. Roisman.

DR. ROISMAN: I'm not sure if is this on?

How about now?

If I could just follow up with a few comments. I mean, as was just stated, you know, there was a question as to whether these chemicals are a priority. Although, what we're really trying to decide today is not whether these chemicals are a priority for biomonitoring, but whether there is evidence to suggest that they should be included on the designated list.

And I just think it's important to keep in mind as you're reviewing this, the criteria for inclusion -- for recommendation as a designated chemical include, you

know, known or suspected health effects. So there does not need to be absolute proof of toxicity in order for these to be chemicals that are considered legitimate for designation. And some of the other concerns that were raised by the presentation we just had, I think, could be, you know, better addressed in a full, you know, toxicological review, which is not what we've done at this point in order to provide the information that's necessary to determine whether or not these chemicals should be designated.

I think that, you know, some additional -- we can certainly do more of a review if we have, you know, additional resources that we can turn to and if the Panel is interested in that, we'd be happy to do it. But I just wanted to encourage you to keep in mind the criteria For designation and the distinction between picking a designated chemical and picking a priority chemical.

I also wanted to say that some of the concerns that were raised have already been addressed by OEHHA in a document that was written in response to some of the industry's concerns. And, again, we can make this available to the Panel. But in particular the PBPK modeling that was run was rerun by OEHHA staff. And they found that the level of D5 in particular was still increasing in fat compartments when the model was run out

to 15 months. And that OEHHA concluded that they don't understand that a steady state is reached in fat in 15 days as indicated in one of the studies that was just referenced.

So there -- I just want you to know that, you know, many of the questions that were just raised have been addressed, you know, in further documents that have been produced by OEHHA. And there's still, I think, ongoing -- there's a lack of consensus on these issues. And there's still a lot that's unknown. And there's still questions about the persistence, the toxicity and the relevance to humans.

I would also add that, you know, I think that there are not a lot of studies looking at these actually trying to measure these chemicals in humans. And there are questions that have been raised about how long ago those studies were done or the methodology that was employed, and, you know to consider -- you know, the way to tell if they're accumulating in humans would be to test humans to see if -- and so it seems like that's another -- there's a lack of good, current data measuring for -- biomonitoring for these chemicals in humans and that's something that the Panel and this Program has the opportunity to, you know, to make happen.

And just on a final point, in terms of the

persistence in the environment, the speaker referenced the Canadian studies that have looked at this and they did conclude that D6, in particular, was persistent in the environment and there were also these studies in the Nordic environment that have found levels of all the cyclosiloxanes, in particular D5 in fish, suggesting that these are persistent in the environment. We haven't yet had the opportunity to review that the area that was presented that they don't bioaccumulate in the environment. And that, in fact, as you go up in the food chain, the levels become lower. But there is still good evidence and it has been concluded by other bodies that these compounds are persistent in the environment and showing up in fish in particular.

CHAIRPERSON MORENO: Thank you.

What I'm hearing was an interest by one of the Panel members for additional information be provided by the industry. And I just want to check to make sure we are consistent with our obligation to the public.

May I request that that information be provided to the Biomonitoring Program, which would then make that available to the Panel and make it available to the public, if we are going to be reviewing it.

Would that be appropriate?

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: Um-hmm.

CHAIRPERSON MORENO: All right, thank you.

Other questions, discussion by the Panel?

MS. HOOVER: Dr. Moreno, can I ask just one question of the speaker?

One of the questions that a Panel member raised was use in California, and I was just wondering, do you have any specific data about the use of these compounds in California and also in dry-cleaning in California?

DR. PLOTZKE: I do not have that information. I think it would be best to talk to the dry-cleaning industry about that. What I did refer to is that we did cover it in our exposure assessment aspect in looking at the risk. And including that in there, there was no risk to humans.

CHAIRPERSON MORENO: Dr. McKone then Dr. Wilson.

PANEL MEMBER McKONE: Yeah, I guess there was -- there's still questions I have. And I guess I can't really resolve these until I see more details.

But when you talked about the dermal uptake experiments, this is a compound with a large -- relatively large KOW. Typically, they're 100,000 or log KOW5, and they're low water solubility. And showing up an hour after application on the skin is quite unusual. But, again, I'd have to look more at what these compounds are.

Typically, fat soluble compounds go into the

stratum corneum and then slowly penetrate through for even days. So the only thing you would see showing up in the blood are the more water soluble compounds, but these aren't water soluble. They're octanol. So you'd have to really look at what's going on with the octanol air or something else. So, I mean, I think chemically they're very complicated.

The other point is there are substances that are very rapidly metabolized that show up at high levels in the human body. Some of the pesticides, because the exposure is continuous. So the persistence in the human body only establishes an equilibrium level, but it doesn't tell you it's not there if your exposures are high.

Of course, we have this question the exposures are -- the loadings are very high. Actually, I located that paper and was reading it during part of this. But nobody's really measured the translation of exposures to uptake very well.

But, actually, what you're suggesting is maybe they do go in fairly quickly and then volatilize out through the lungs, which they do have a high vapor pressure.

If they metabolize rapidly, I think the other question is taking the whole pathway of the metabolites and whether there's a persistent metabolite that we may be

concerned about.

So I guess what it takes me back to is there's enough open questions on this that I would kind of go back to say these are in such large use and it's such -- again, it's a changing market issue and siloxanes are substituting and coming into markets in new functional areas. You know, I think the Committee -- or the Panel has to struggle with the question of whether they should be designated just because they really fit into this category of substances that are in a rising market share and really raise some interesting questions.

Not that we're trying to -- you know, we're not -- I don't think we're trying to say anything about toxicity at this point, but whether they can be biomonitored is the issue.

DR. PLOTZKE: If I can address that question on the exposure part of it.

Yes, I've seen that article too and what that is is loading. But what we have actually done, in addition to that, is look at the behavior on the skin. So we actually have published studies showing how much volatilizes off the skin during typical type of applications, as well as what does penetrate if it does. And if you look at the three materials, you'll get penetration of D4, much less with D5 and essentially zero

with D6.

And those are -- even D4 is basically about .5 percent. And so, I mean, it's a very small amount that actually penetrates. Most of it volatilizes. Over 90 some percent of it volatilizes off the skin. So those loading rates are high, but over 90 percent of it will volatilize right off the skin.

CHAIRPERSON MORENO: Thank you very much. Thank you for your public presentation. We're still between public presentations and discussion. But I did get one more request from John Dunlap.

Oh, you do have one more question. I apologize. Go ahead.

PANEL MEMBER WILSON: Sorry.

MR. DUNLAP: While she's coming, I think I can answer the question that Dr. Solomon raised. My name is John Dunlap. I'm an environmental consultant. I used to work at CalEPA. I was a former CARB chairman. I represent Green Earth Cleaning, and would be pleased to share with you and the staff the information about the market penetration that that company has, and about their efforts to work to provide, what we believe, a much better solution for Perc in dry-cleaning.

So we'd be pleased to share that. That's all I wanted to say, Mr. Chairman.

CHAIRPERSON MORENO: Thank you.

PANEL MEMBER WILSON: Dr. Plotzke, thank you very much for that presentation. And I guess it's also relative to Mr. Dunlap's point that one of the things that we're coming up against here, and that what you're struggling with, is that we haven't decided yet in the State of California what are the technical measures or the range of technical measures that would designate a substance of high concern, for example, or a substance that is a genuinely safer alternative.

And so we're having to make decisions based on the best information we can get and make a determination. And so I appreciate all of the input on that. And what I'm trying to, I guess, justify is the -- that your, you know, argument about the polarity of the substance and that would -- and the pharmacokinetic modeling that that would -- you know that indicates that this will be rapidly removed versus, you know, some of the other evidence that we have about -- or that we provided that D5, in particular, partitions to air, water and soil, but mostly ends up in soil and sediment. That the probability that D5 will biodegrade in water and soil is essentially zero, according to Environment Canada.

Environmental monitoring in the Nordic countries found D5 to be dominant cyclosiloxanes in fish livers and

marine mammals. A number of others. A 1982 survey of human adipose tissue found D5 in 28 of 46 people sampled. And then, again, the Swedish study of breast milk.

So I guess my question is that are those findings the result of methodological or laboratory errors or as Dr. McKone suggested, is it -- are they explained by more ongoing exposure that's occurring more continuously?

DR. PLOTZKE: And I'll kind of try to break them up again just to cover the various points. I'll start with the human aspect of it and the fat samples. I've reviewed that work. It's very hard to tell. There's very little information around any QCs that were used in the laboratory. And we do have significant concerns around contamination. And we've even seen in our own laboratories that if you've worked with those materials, they -- you know, basically the previous day at any higher concentrations and then try to analyze in a trace level, you're going to get contamination.

So they do stick to the surface of the glasses things like that, the vials. So you have to be extremely careful. So I can't really say on the EPA work given the timeframe it was done in and without the detail whether or not there were any lab QCs. I can tell you what we do and what others do.

In fact, we were just in Norway two weeks ago

monitoring with them and we actually run air monitoring in the laboratory to ensure we know the background levels. We carry matrix blanks into the field with us to ensure we know that, you know, they're not getting in there by something that we're doing or something that we're bringing them in contact with.

So I think we can know from this point forward, there's a lot of information. We've been working with Norway on the monitoring program. They are now in agreement that they did not have those QCs in place when they collected those samples. I think you will find these materials in some areas of the environment. But what's important is that some of the trace levels that have been reported are at or below the level of true detection if you run the appropriate QCs. And I think we're all in agreement with that now that that is very critical and that's why we have this partnership, the inter-laboratory comparison of looking at these materials in the various matrices. And that is really critical going forward in asking the questions where are they truly being found.

The other aspect about the persistence component in Environment Canada, we actually have been working with Environment Canada all along, but even more so since their preliminary assessment. And that is really what's only available today is their preliminary assessment. And so

we have actually been providing data, since that preliminary assessment, on the degradation and potential for bioaccumulation of these materials.

Even though their final assessment is not out and is not available yet, and I can't tell you what that would be, but I know that they have acknowledged now uncertainties around those two aspects of these materials, and that we have put data in their hands to show degradation of these materials.

In addition, they've even had some of their own internal experts review, for example, the hydrolysis data that was provided looking at the degradation in water. And their own expert agreed with the study design that we conducted and the half-lives looking at these materials in water. So a lot has happened since the preliminary assessment.

And I think what's really important is to look at all of that information. The degradation in soil is published. These materials clearly degrade in soil. The degradation pathway in the atmosphere is published. This is all peer-reviewed literature that's out there. So there are lots of examples out there actually showing that these materials do degrade.

Will they be found in the environment? I think you can find them in the environment. But the real

question is are they found at levels that there's any concern to the environment and then do they become available to humans?

And I think a lot of the information that we've generated in our program demonstrates that these materials will not accumulate -- bioaccumulate in the environment. And we can certainly share the Lake Pepin data, which shows they don't biomagnify. And we have a very good understanding of human exposure routes and the kinetics associated with that and how the materials then will behave in humans. And I think if you look at the kinetic data that you can clearly see by the relevant routes of exposure these materials basically leave the blood and plasma very quickly.

PANEL MEMBER BRADMAN: I have a follow-up question.

During your presentation, you seemed to indicate that measuring metabolites in urine might be a way of getting around the sample contamination or laboratory contamination during measurement. And I'm curious if there have been measurements of these metabolites, and if there are methods available?

DR. PLOTZKE: There are no direct methods available for each one of the individual metabolites. We've looked at metabolism through our mammalian studies

and even our human studies using profiling -- radiolabeled profiling. So that's how we've done it after we've conducted an exposure.

But from a direct standpoint, looking at each one of the individual metabolites, there would need to be method development.

PANEL MEMBER BRADMAN: And so you're using like carbon 13 label?

DR. PLOTZKE: Carbon 13, yes.

CHAIRPERSON MORENO: Additional questions?

PANEL MEMBER LUDERER: I just actually did have one quick question that relates to it. You said that they're detectable in plasma after dermal application and then they rapidly disappear. And I'm wondering what -- is there evidence that some of that may not be cleared, but go to adipose tissue, for example, since they are very lipophilic?

DR. PLOTZKE: They are lipophilic and you will see some distribution to, you know, adipose tissue. But also if you look at the kinetics of it, as soon as your blood levels drop, then there's movement out of the adipose tissue back into the blood and clearance. And the clearance occurs through either exhalation or through metabolism and then elimination in the urine.

So it's a dynamic process, so it will

redistribute back out and clear back out.

CHAIRPERSON MORENO: Additional questions?

PANEL MEMBER SOLOMON: Just to clarify. So what you're basically saying is that these chemicals in the body appear to behave as a VOC, essentially? That they're absorbed through the skin. They're absorbed through inhalation. They're distributed rapidly to fat compartments. And then excreted through both exhaled breath and the liver through bile.

I understand not through urine, is that not really --

DR. PLOTZKE: Yeah, metabolized in the liver to water soluble materials that then are excreted --

PANEL MEMBER SOLOMON: Can then be excreted through the urine.

But then -- so basically it's behaving like a VOC. And then, you know, the question in terms of biomonitoring, you know, does involve things like sample handling. And the likelihood that you will find something really depends on exposure frequency. And, you know, so depending on use patterns, exposure frequency, if it's pretty frequent, as appears to be the case with these, one might be picking it up just on that basis alone. There are a number of VOCs that are biomonitored, so it's certainly, you know, feasible to do.

Perchloroethylene, for example, is on the designated chemicals list, and has a, you know, sort of similar, sort of, time period and so forth in the body to what you're describing here. So it doesn't seem to be prohibitive.

One of the questions I had is about limit of detection in the various studies, specifically the ones that did not detect the -- Flassbeck studies, which did not detect anything in the women who didn't have implants. And I was just wondering if you could clarify for us what the limit of detection was in those studies?

DR. PLOTZKE: Yeah. I believe their limit of detection, I don't have it in front of me, it was probably around 20 to 50 parts per billion.

CHAIRPERSON MORENO: Okay. If there are no more questions, I'd like to -- there's been a request to have Mr. Dunlap return to answer a question. And while he's coming we'd like to read one of the Emails that has come in.

OEHHA DIRECTOR DENTON: We have three Email comments which have come in. And the first that I'll read is from Rebecca Sutton and she's with the Environmental Working Group.

"The Environmental Working Group supports biomonitoring of cyclosiloxanes

as part of the California Environmental Contaminant Biomonitoring Program. Three linear siloxanes share many chemical, toxicological and use properties with the cyclosiloxanes identified by OEHHA. Hexamethyldisiloxane, decamethyltetrasiloxane and octamethyltrisiloxane are found in cosmetics, paints, pharmaceuticals and other everyday products, and have been identified as priority persistent, bioaccumulative, toxic compounds by other countries. Given the chemical similarities, it may be possible to bundle measurements of the linear siloxane with the cyclosiloxanes at relatively little cost and we suggest the Science Guidance Panel consider this option."

CHAIRPERSON MORENO: Thank you. We have one question from Dr. Wilson and then I think Dr. Petreas had something she wanted to add. But could we get to Dr. Wilson's question first.

PANEL MEMBER WILSON: Dr. Dunlap, thank you for

your comment earlier, and I wanted to follow up. The Green Earth that you're referring to is D5, is that right?

MR. DUNLAP: Yes.

PANEL MEMBER WILSON: I'm just curious if you are able to comment on the sales or use trends in the state over the last few years.

MR. DUNLAP: I would be pleased to secure that for the Panel. I don't have it at my finger tips.

By the way, I intended today to just monitor the Biomonitoring Panel.

(Laughter.)

MR. DUNLAP: So you drew me up here with a question, Dr. Solomon did. But I'd be pleased to get a quick turnaround and get you the information.

And by the way, I appreciate very much the commentary about dry-cleaning and you drawing it to attention. It's my belief, as a former regulator, and I work with a lot of green-tech companies, that the Green Earth cleaning product is much improved over Perc. And so this company, a good company, is looking to be able to earn market-share as a better alternative. And so we've been working very closely with our friends and colleagues from SEHSC. We've been very pleased with the coordination that they've shown us. And they've indulged us by keeping us abreast of the research and the dialogue that's going

on.

So for what it's worth as a commercial company out in the marketplace, we couldn't be more pleased with how open SEHSC has been with us in trying to illuminate what issues we need to be aware of and how it's going. So we're an open book. We'll be pleased to share that with you.

PANEL MEMBER WILSON: Just one follow-up question on that. I guess as the State moves ahead with its phaseout of Perc, given the other technologies that are available in that particular industry in dry-cleaning, do you anticipate that the use of D5 is going to grow in California?

MR. DUNLAP: It's our belief, yes. And we think that there's a robust market opportunity as well, but there's some other things that are emerging. You know, there's some competition in the market. It's not assured that the Green Earth product will be the one that will, you know, capture all of the market share. But they're being aggressive in trying to talk about the attributes, the benefits and the ease of use and how the consumers seem to be reacting very positively to it.

But the one thing the company is absolutely committed to is to being active with what's going on in the environmental area in tracking and trying to

participate proactively. So I wish I had more definitive things to say. We work through our association colleagues and friends and we'll make sure we share with you the information about what's going on in the market as we know it.

PANEL MEMBER WILSON: Thank you.

CHAIRPERSON MORENO: Thank you. I want to try to move this along. We need to get to lunch, because we have a lot more to talk about when we get back.

Dr. Petreas, did you still want to add some comments?

DR. PETREAS: I had a question for the previous speaker, Dr. Plotzke. If she could make available to us the information she has on methodologies and contamination and the inter-laboratory studies as we get up to speed to help us start the right way.

CHAIRPERSON MORENO: Okay, did you hear that?

DR. PLOTZKE: Yes.

CHAIRPERSON MORENO: Okay, thank you.

MS. DUNN: I'd just like to clarify for the people who will be sending us comments that it's most helpful if they can be sent electronically, so then we can easily share them with the Panel and the public.

CHAIRPERSON MORENO: Dr. Denton, could you read the other comments that were Emailed to us.

OEHHA DIRECTOR DENTON: Okay. We have two more. This is from Rachel Washburn. And Rachel is a Ph.D Candidate at UCSF.

"Dr. Wilson raised the issue of suspicion of risk versus clear evidence of health harm in reference to your discussion of cyclosiloxanes.

"During the last discussion on flame retardants, Dr. McKone raised the issue of monitoring for chemicals or emerging concern.

"It seems that if you are going to be biomonitoring for emerging chemicals, the issue of suspicion of risk versus evidence of health harm will continue to persist. How do you propose to deal with this tension?

"Thank you very much for your time and for providing a webcast for those of us who cannot make the meeting in person."

CHAIRPERSON MORENO: Would anyone want to provide just a brief comment in response to that question that came in?

OEHHA DIRECTOR DENTON: It's the issue of risk

versus evidence of health harm.

PANEL MEMBER WILSON: I would, sure. And I think it's, you know, a fundamental point and I think a great question. And I certainly -- I think that we have demonstrated that it makes sense for us to build -- improve our knowledge base and to take action, not simply on clear evidence of cause and effect, but much further down the continuum towards scientific suspicion of risk.

And I think, you know, it's -- this last discussion that we've just had is sort of illustrative of that tension. But I think we are seeing, you know, developmentally within the European Union, for example, decision making that is finding it appropriate to -- for governmental bodies to act on reasonable grounds for concern, for example, as compared to clear evidence of cause and effect.

And that if we're going to have a functioning program -- Biomonitoring Program that we can contribute to

the body of evidence that is going to allow us as a state to make more informed decisions along that continuum. But I'm certainly not calling for the need for clear evidence of cause and effect as the basis for decision making.

CHAIRPERSON MORENO: All right. Thank you.

PANEL MEMBER BRADMAN: I actually have a question almost directed to Sara related to what you just said.

This is back to your presentation. For designated chemicals, you had the quote, "...known to or strongly suspected of adversely impacting human health..." and that's from the statute, and then, of course, there's the CDC. And then our panel can recommend additional designated chemicals.

And I know you commented on this, but are we constrained by that first language in the statute to only designate -- you know, identify designated chemicals that meet those criteria?

MS. HOOVER: I'm going to defer to our lawyer on that question.

(Laughter.)

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: Well, it's interesting, because in terms of the actual language in the statute, there's two different ways that chemicals are described. One being -- or this particular issue is described, one says is part of the definitions of

designated chemicals, and it talks about chemicals that are strongly suspected of causing harm.

So that's a little different than what the actual criteria under the -- for the Panel to designate chemicals actually says, known or -- "...known or suspected health effects..." It could be a drafting issue, I don't know. But given the fact that this is specific criteria for your panel, you'd want to -- I would recommend to you use the criteria that the law says for you to use in terms of designating the chemicals, and that includes, "...known or suspected health effects...", not strongly suspected.

So, you know, obviously you don't have to -- as Dr. Wilson said, find that there's, you know, an absolute correlation between cause and effect, but at the same time you should at least suspect that health effects are resulting from some level of exposure.

PANEL MEMBER BRADMAN: So related to that --

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: In terms of -- and just one additional point. When you get to the stage of designating priority chemicals, there is also the opportunity for you, as a panel, to develop other criteria, but that item isn't included in the list of considerations for designating chemicals.

PANEL MEMBER BRADMAN: Right. So related to that, having a chemical designated on our list of

designated chemicals, doesn't mean it's causing harm in the population, and it's not necessarily an indictment of any given compound or class of compounds. So I think maybe it's important that people understand that. That we're not making judgments on the danger or safety of any given chemical, but that we think it's maybe worthy of understanding what the exposures are.

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: That's exactly right.

CHAIRPERSON MORENO: Thank you for that clarification. I appreciate it.

Can we read the next Email, please.

OEHHA DIRECTOR DENTON: It's the next Email and the last Email.

This is from Betsy Carlton. Betsy is a Ph.D, DABT. The only identifying information I have about Dr. Carlton is that she's at us.rhodia.com.

And she says, "My concerns for biomonitoring for these substances are three-fold."

First, "Use of existing blood/plasma samples do not control for potential contamination during collection and storage."

Second, "Control of lab contamination is very difficult, potentially providing false readings."

And third, "Evaluation of the cost-benefit and

the difficulty of the analyses resulting in higher costs seems to be a poor use of the limited resources available in California. There are much higher priorities for these limited resources than the siloxanes."

CHAIRPERSON MORENO: All right. Thank you for the input from --

DR. ROISMAN: If I could just respond. Again, it sort of raises the question, I think, that a number of those concerns are particularly relevant to the decision about prioritizing chemicals. But it is a different set of criteria that we're using for determining designation of chemicals. And I just wanted to remind the Panel and the public to keep those distinctions in mind.

CHAIRPERSON MORENO: I see Mr. Dunlap at the podium, but that was just public comment and we're not --

MR. DUNLAP: But before that, there was a point made about being on the designated chemical list whether it would have an effect in the market. And the answer would be yes. And that's one of the things that we're watching very closely.

So I don't want any of you to think that the action today is, you know, advisory only and that there wouldn't be an interest or ramification in the marketplace. There would be. And so that's why companies like ours watch very closely with your activities. So

you've got a tough job and we acknowledge that.

CHAIRPERSON MORENO: All right.

Thank you.

Dr. Lipsett.

DR. LIPSETT: Yeah, I wanted to just make one other comment and maybe this is brought out before. But in terms of doing biomonitoring, we've talked up to this point about looking only at blood and urine samples, but there are other biospecimens that could be used, including exhaled breath condensate, which is something that could also be used to look at other VOCs. And to the extent that this is exhaled through the breath, this might be a method that we could adopt later on, if need be, if this ends up as a designated priority chemical.

CHAIRPERSON MORENO: Okay. Panel members it's a quarter to one and we would like to take an hour for lunch and we have much more to talk about when we come back. So, at this point, I would ask if anyone on the Panel would like to suggest a recommendation. And, if not -- well, a recommendation.

Dr. Culver.

PANEL MEMBER CULVER: I recommend that we defer decision on this group of chemicals until we have more of the information that we now understand is available.

PANEL MEMBER BRADMAN: I would agree with that.

I mean, given the discussion we've had and the requests that have gone out, I don't think it will hurt for us to look at that.

CHAIRPERSON MORENO: Okay. Discussion?

Dr. Solomon.

PANEL MEMBER SOLOMON: I'm not sure if we're proposing to defer until after lunch, which I would certainly heartily agree with or to defer to the next meeting. But it seems to me that we do have a fair amount of information before us at this point.

You know, I want to, again, just sort of go back to this issue of whether we're designating or whether we're, you know, prioritizing. And for designating, I'm not really sure that getting, you know, additional detailed information about some of the points that were raised will make a whole lot of difference. We know that there is very wide spread use in California. We know that there is extensive use in consumer products and, therefore, potential for consumer exposure. We know that there is absorption through the skin and inhalation pathways. And, you know, we know that it is feasible to biomonitor for these chemicals. Although, you know, of course, as with the other chemicals that we've looked at today, there are sort of, you know, various logistical issues at the laboratory level that will need to be

surmounted before anything could actually go forward.

And so, you know, even in the absence of, you know, information about how much these chemicals actually bioaccumulate, since there is a direct consumer product, mediated, personal exposure pathway, I don't think that the -- sorry, the persistence and bioaccumulation data will necessarily change anything there.

In terms of the toxicity -- well, you know, I haven't done an extensive toxicity review. I did look a little bit at the Dow Corning study that showed uterine adenocarcinomas. And that's a fairly worrisome finding and striking and was actually sufficient to get U.S. EPA to issue a bulletin, you know, that sort of flagged that information.

And so, you know, I think that there's enough to certainly meet the suspected health concern language.

So, you know, my proposal would be a bit different, would be to, you know -- and I could make my proposal, but I think we're now discussing Dr. Culver's.

CHAIRPERSON MORENO: I have a question for counsel. We have a recommendation and a second supporting a Panel member to defer on a recommendation. Is that really an action item or would the -- and if it's not really an action item, are we looking for recommendations that would take action?

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: Well, we haven't adopted the Robert's Rules of Order. And so -- but it would seem to me that you may want to just have a vote on the initial suggestion that has been seconded. And then depending on the outcome of that, you might have a second vote.

CHAIRPERSON MORENO: All right. Thank you.

Further discussion on the proposal that Dr. Culver put out?

Dr. McKone.

PANEL MEMBER McKONE: Is there a way to -- I mean, do we have to move ahead on this one or can we sort of revise the recommendation, because I think Dr. Solomon raises some good points. I would favor a recommendation that moved ahead but recognized -- for me, the concern is that there's not a high likelihood of finding the substance. That's the question. Not, you know, whether this -- I think this class of compounds is important for getting information on. So I find that appealing and would favor designating it.

But I think there are enough concerns about lack of feasibility. We haven't really confirmed feasibility of whether we're going to find, you now, not quite the same as other chemicals where we're fairly confident that we have the method and everything worked out. Am I

correct in saying that we're not as certain that we're going to really find it at the levels or with the -- or am I -- is that not --

DR. FLESSEL: There's certainly uncertainty on our part.

DR. PETREAS: From what we heard, it's difficult to measure, but it is there.

PANEL MEMBER McKONE: It is there, okay. Well, I don't know if that -- you know it's like we have two tracks kind of going, I think. And I just wanted to bring that up

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: Well, one of the things that you should probably take a look at -- I don't know. I'm assuming that you have a copy of the statute. If not, there's -- as mentioned before, there's two different criteria -- level -- or lists of criteria, one for prioritizing and one for designating. And in that prioritizing, which you're not doing here right now, you consider things like the limits of laboratory detection, and the likelihood of being able to detect a chemical. Some of the things like likelihood that the chemical actually is a carcinogen or toxicant, the degree of potential exposure, that sort of thing. So you do that when you're kind of prioritizing.

But what you're looking at here is the exposure

again, but whether or not there's known or suspected health effects, availability of analytical methods, not so much the application of them in the specifics, and availability of samples and costs. And so some of what I think you're wrestling with is still should -- the difference between prioritizing and designating.

But, you know, if, for example, you know, kind of back to your main question. If Dr. Culver wanted to withdraw his suggestion and somebody wanted to make a different one in terms of recommendation, that's fine. But at the moment, the only one that's been presented was Dr. Culver's.

CHAIRPERSON MORENO: Well, we need to move -- thank you. You've been very helpful with that.

I'd like to move the Panel forward in just making a decision at this point and based on counsel's recommendation the standing recommendation for Dr. Culver with a second. Could you please state it one more time, Dr. Culver.

PANEL MEMBER CULVER: Will I what?

CHAIRPERSON MORENO: Restate your motion.

PANEL MEMBER CULVER: My recommendation is that we -- what did I say? -- defer further decision on this until we have more of the information that we know is available to review.

CHAIRPERSON MORENO: Thank you. We have a second. So I'll go ahead and ask for a vote.

Dr. Zeise.

DR. ZEISE: I will help you count.

CHAIRPERSON MORENO: Thank you.

DR. ZEISE: So in favor?

OEHHA DIRECTOR DENTON: I think the question is if in favor of the motion as you go through the line, if you could say yes or no, okay.

DR. ZEISE: If in favor of the motion, if you could say yes or no?

PANEL MEMBER WILSON: I have a clarifying question, I'm sorry.

CHAIRPERSON MORENO: Yes, do that first.

PANEL MEMBER WILSON: And that is that we're deferring -- I guess is there a time limit on this or are we -- we're looking at until the information is provided I guess is the question.

PANEL MEMBER CULVER: Not only provide it, but it will give us an opportunity to look at it.

CHAIRPERSON MORENO: I think if we vote to -- we agree to defer on making a recommendation to add this to the designated list or not and then it could be followed with guidance by the Panel to the Program staff as to what particularly we would like to have, so that when we have a

discussion on this later, we can have the information that's necessary to then make -- someone may want to make a recommendation to add it to the designated list. Would that be correct?

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: (Ms. Monahan-Cummings nods head.)

PANEL MEMBER KAVANAUGH-LYNCH: I'm sorry. I have a clarifying question also.

Dr. Culver, could you clarify maybe using the criteria that are in front of us which criterion or which of the criteria you would like more information on?

PANEL MEMBER CULVER: I think we're talking about recommending additional designated chemicals, are we not? Is that the criteria that we're addressing?

PANEL MEMBER KAVANAUGH-LYNCH: Yes.

PANEL MEMBER CULVER: What is your question then?

PANEL MEMBER KAVANAUGH-LYNCH: I'm thinking of your request for additional information and thinking what additional information would help me. And I can't think of anything in those criteria that there is more information that I would find helpful. And so I'm curious what information that had to do with these criteria you would find helpful.

PANEL MEMBER CULVER: I would certainly like to see the information that's available on biopersistence,

the PBPK information and the information on the toxic effects that have been alleged -- that have been identified for these chemicals.

I'm only asking that we -- it seems that there is a fair amount of information here that we have not really seen yet or I haven't seen yet. And I'm not comfortable in making a decision with regard to the definition of what a criteria chemical is for me to answer that question yet. So I'm only asking for time.

PANEL MEMBER KAVANAUGH-LYNCH: I wasn't challenging that. I was just asking what specific information would help you, so you answered that. Thank you.

PANEL MEMBER CULVER: Thank you.

PANEL MEMBER SOLOMON: So if I may just follow up.

So it sounds like there's some questions around the top two criteria, whether there's exposure or potential exposure to the public or specific subgroups, because some of the additional information that would come in might relate to that. And so if there's -- presumably a panelist should vote yes on this if they are concerned that there may not be exposure or potential exposure to the public or specific subgroups to these chemicals.

And then the other question has to do with

whether there are any known or suspected health effects resulting from some level of exposure.

And we have been provided in the staff presentation with a fair amount of information on both of those. But, you know, obviously if that's not sufficient, then it would make sense to vote yes and to await further information.

PANEL MEMBER BRADMAN: I just want to comment too, because I had supported Dr. Culver's recommendation. For me, I just feel like I want more information. That there seems to be a lot out there that I haven't looked at yet and that I can make a more informed choice.

When I look at these criteria, I would probably -- you know, I know how I would probably recommend in terms of a listing as a designated chemical or not. Rather just I feel like there's a certain level of ignorance I have and I'd like to kind of fill that gap.

CHAIRPERSON MORENO: Additional discussion? I want to make sure everyone has an opportunity to discuss this proposal.

So now I'll call for a vote asking for those that are in favor of Dr. Culver's proposal will signify by yes.

DR. ZEISE: Okay. So those in favor if you can indicate a yes.

Starting with Ulricke Luderer.

PANEL MEMBER LUDERER: Yes.

DR. ZEISE: Dr. McKone?

PANEL MEMBER McKONE: No.

OEHHA DIRECTOR DENTON: If you could speak directly into the microphone and then Dr. Culver was next.

PANEL MEMBER CULVER: Yes.

CHAIRPERSON MORENO: Yes.

PANEL MEMBER WILSON: No.

PANEL MEMBER BRADMAN: Yes.

PANEL MEMBER KAVANAUGH-LYNCH: No.

PANEL MEMBER SOLOMON: No.

CHAIRPERSON MORENO: So what is that?

DR. ALEXEEFF: Four to four.

OEHHA DIRECTOR DENTON: So the count was --

DR. ZEISE: Four to four is what we counted.

OEHHA DIRECTOR DENTON: Four noes and four yeses.

(Laughter.)

OEHHA DIRECTOR DENTON: Okay, counsel.

(Laughter.)

CHAIRPERSON MORENO: Are you going to put us through the exercise?

OEHHA DIRECTOR DENTON: What does that mean?

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: That means that generally you have to have a majority of the quorum vote to positively pass it. So I would say that it didn't

pass. It's not a majority. You have to have five.

CHAIRPERSON MORENO: So it did not pass.

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: So it didn't pass.

CHAIRPERSON MORENO: It didn't pass. Well, at this point, we could ask if there's another recommendation. But I think I know -- well, we could ask for a recommendation and see what the outcome is, but --

MS. HOOVER: Actually, I think we really need to take a break for the court reporter.

CHAIRPERSON MORENO: I see.

MS. HOOVER: We can't -- I think we need to defer further discussion till after lunch.

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: And just a reminder not to discuss it during lunch either.

(Laughter.)

CHAIRPERSON MORENO: All right. It's five after -- thanks for bringing it to our attention. It's five after one so we will return at five after two.

All right. Thanks.

(Thereupon a lunch break was taken.)

AFTERNOON SESSION

CHAIRPERSON MORENO: All right. Welcome back to the Scientific Guidance Panel meeting. We have all of the Panel members here back. And I'd like to pick up where we left off.

We left off with a motion -- there was a proposal that didn't have a majority vote. And so, at this point, I'd like to actually -- it seems that we're at a stalemate with this regard on whether or not we're going to take additional action or make additional recommendations.

So I thought, if the Panel members don't mind, I'd like to ask Dr. Denton if she has a suggestion on how we might be able to take some next steps.

OEHHA DIRECTOR DENTON: Obviously, this is a new program for all of us and we're feeling our way through. And we look very seriously upon the recommendations that the Panel is giving us on these chemicals. And I think that the ambivalence of the Panel on this last item, the four to four split vote, indicates that probably the best thing would be for us to gather the information that has been promised, that would be provided to us. We could do an additional literature search. We could provide that information to the Panel and I think turn it around in a fairly short time and bring it back to the Panel to see if there could be more of a consensus on how we ought to

approach it. So I think a little time is warranted at this point.

CHAIRPERSON MORENO: Could the Panel members at this meeting now make recommendations to Program staff as to what information would be necessary so that when we meet again, everyone on this panel is comfortable with a vote of whether or not to designate this group -- this class of chemicals.

OEHHA DIRECTOR DENTON: Certainly. I think if you recommended that we obtain the information that the speakers, the public commenters promised that we'd do an additional literature search and any additional information that you would want to be provided, that's appropriate. And we can bring it back and consider it again.

CHAIRPERSON MORENO: All right. Well, then I'll ask the Panel members if that would be satisfactory.

PANEL MEMBER SOLOMON: I have just one note of caution, is that I guess I would like to hear something a little more specific from the Panel members about what really would make -- you know, what pieces of information are really missing from the current package, because otherwise we can end up in these open-ended situations, where we say oh, well, we would welcome more information. And we can get, you know, volumes of information sent to

the Panel from numerous interested parties on every single one of the chemicals that we're considering designating, and sending the signal that we're open to, you know, delaying and looking at everything that anybody might choose to send us is, I think, risky, just because it can, in the future, bog down our process.

And I think one of our goals has been to really look at the key pieces of information that we think we need in order to meet our charge and stay focused on those. And if we feel that those pieces of information are there, then, you know, we're able to move forward with a decision.

CHAIRPERSON MORENO: That's a very good point. I think we've determined earlier today that information that was offered by industry representatives today would actually -- wouldn't be coming to the Panel. They'd be going to the Program staff. And Program staff will take that information and also obtain additional information under the guidance of this panel. And I think we can make those recommendations. I would suggest that we make those recommendations right now to Program staff as to what information is necessary and for the following reason; for every member of this panel to feel comfortable to vote yes -- yes or no vote on whether to designate this class of chemicals.

PANEL MEMBER CULVER: I would have a further suggestion that we limit information to only peer-reviewed information.

DR. ALEXEEFF: George Alexeeff.

Well, I was hoping that we could include a report that OEHHA prepared for the Air Resources Board on siloxanes.

PANEL MEMBER CULVER: Okay.

PANEL MEMBER WILSON: In addition, I think we've learned a lot from personal communications that staff have had with experts throughout the U.S., for example, on the diesel exhaust question, that I think has been valuable for us. I wouldn't want to exclude that information in this matter.

PANEL MEMBER CULVER: May I respond to that?

I agree with you that there is a lot of important information that has not been peer reviewed. But if we receive that sort of information, then this group needs to serve the function of being a peer-review group. We need to decide among ourselves whether we classify that information as scientifically supportable.

CHAIRPERSON MORENO: Would it be satisfactory to Panel members if information is brought to the attention of the Panel members by Program staff and it's not peer reviewed, that the Program staff should make it clear that

it's not peer-reviewed information that is being presented to us?

PANEL MEMBER WILSON: I mean, it's apparent, I think, in the citations that have been given thus far that personal communications and also reports have been cited. So I suppose further clarification might be helpful. But for -- and I guess another area of information that I've specifically requested has been from the industry representative that is useful to us on sales trends and uses of these substances in California. And that's not going to be peer reviewed, but is important information.

PANEL MEMBER BRADMAN: I would say I'm also particularly interested in the laboratory feasibility and QA/QC issues around actually conducting the meaningful measurements.

PANEL MEMBER SOLOMON: I would support the Chair's recommendation that the origin of information be clearly identified. And I agree, when we look down the list of criteria that this Committee is charged with evaluating, frankly, you know, if we restrict it to peer-reviewed information only, some of these questions just aren't amenable to being addressed in that way, for example, you know, the need to assess the efficacy of public health actions or the availability of adequate biospecimen samples. These are things that we need to

gather through sort of a broader look and a discussion with laboratory experts and such. So I don't think we should limit ourselves.

PANEL MEMBER CULVER: My comments were with regard to scientific information that would allow us to determine whether or not there are significant health effects. The issue of how widely the possible public exposure is doesn't come into that category. I'm only talking about the biological and health information.

CHAIRPERSON MORENO: All right. So we've had some suggestions made by Panel members with regards to importance of peer-reviewed literature when it's appropriate to use -- to rely on that. Also, nonpeer-reviewed literature and there's instances where that's most appropriate. And I think the points have been stated very clearly.

If I may ask the Panel members, is there anything else the Panel members would want -- now that we have the Program staff here, anything else you would want clarification on or information that was already presented or do you need anything else in terms of information that wasn't presented today, so that when we come back and address this topic again, everyone of us will have the information we need to make a decision?

PANEL MEMBER WILSON: I guess the three things

that I think are important to me:

One, is the concern from the industry representative that existing studies pertaining to the bioaccumulative properties of these substances are invalid for methodological and laboratory contamination reasons. I would be interested in your assessment of that claim.

And, second, the information -- if there is additional information on the hazardous properties, and toxicity -- I guess toxicity questions. If there's additional information beyond those that were provided to us.

And third, information on uses and expected uses in California, not only in dry-cleaning, but in other products as that information is available.

CHAIRPERSON MORENO: Okay, thank you. Additional recommendations, requests of the Panel members to Program staff?

Actually, Dr. Culver and then Dr. Luderer.

PANEL MEMBER CULVER: Well, let Dr. Luderer go first, because mine is a little bit off the track.

PANEL MEMBER LUDERER: I just wanted to add to the things that the Panel members had already mentioned that other types of information that -- of the types of information I think would be useful would be information that was mentioned earlier about dermal uptake of these

compounds and measurements and plasma. So in addition to the methods for measurement levels in plasma, as well as the metabolism of these compounds.

Something that we didn't really talk about, but it sounds like if these are excreted in the urine, that something down the road in the future that might be more feasible than measuring the parent compounds might be measuring metabolites. So I think it would be useful to have that information.

PANEL MEMBER McKONE: While on that topic. One thing we should add that came up is the feasibility of breath samples, because these are volatile. So the best biomarker might actually be breath and/or some other biological medium.

DR. ALEXEEFF: I didn't catch that. I'm sorry, could you please repeat that.

This is George Alexeeff.

PANEL MEMBER McKONE: I said, because the discussion went to volatilization through breathing, it would indicate that for these compounds breath samples might be -- it's not my point. It was actually Dr. Lipsett's point.

PANEL MEMBER CULVER: One of my underlying concerns, I think, is that not -- that we don't just by rote add every single chemical or designate every single

chemical as a potential designated chemical. We have two screens. We have the pre-screen, which provides the first list, and then the second screen, which identifies the ones that we want to go ahead and actually do work on.

So most screens have to perform a function. And we have to look at each chemical carefully before we decide that it is a designated or a -- is potentially a designated chemical. And I'd like us to consider those very carefully. And maybe we need better criteria to define that screen. It's rather loose at the moment.

PANEL MEMBER BRADMAN: I have one more just specific comment or request.

CHAIRPERSON MORENO: Sure, Dr. Bradman.

PANEL MEMBER BRADMAN: The Email I think that was from the Environmental Working Group asked about linear siloxanes. And maybe you can provide us some information on that and whether those could be bundled in the same analysis with the cyclosiloxanes and if there's any relevant information about those.

DR. ZEISE: So moving to the -- Lauren Zeise with OEHHA. Just wondering if, with the linear siloxanes, you're asking for us to broaden, again, the class, because what we had done, with building on the Panel's recommendation, to look at D4 and the methylsiloxanes, but focused on the most similar to the D5 rather. Are you

asking for a broadening?

PANEL MEMBER BRADMAN: Yes, I guess I am. I just feel like I want to be responsive to those public comments and learn more about those.

CHAIRPERSON MORENO: Anymore requests of the Panel to Program staff?

If not, then Dr. Zeise.

DR. ZEISE: Could I just ask for a little bit more clarification on what you would be looking for for the methylsiloxanes, if you want a greater -- another write-up similar to what we have on the possible designated chemicals or just what level of response are you looking for on that?

PANEL MEMBER BRADMAN: Well, in the comment we got by Email -- and perhaps there's more detail available on that. And if I understood correctly, these compounds are similar chemically to the other cyclosiloxanes in that they potentially are analyzable with the same kinds of methods. So if they're kind of, in part, of the class -- and again, I mean, here's where I would need more information about -- that wouldn't, in fact, be similar to what was provided in the write-up, you know, are they widely used? Are there similar health concerns as with the other compounds? Maybe we should be considering these in this group.

DR. ZEISE: Okay. I just wanted to -- Lauren Zeise, OEHHA again. I just want to clarify that this could potentially be a very large class of chemicals. And initially we had considered the methylsiloxanes, so we are potentially talking about a very large number and a complex set.

CHAIRPERSON MORENO: Well, if I could -- Dr. McKone.

PANEL MEMBER McKONE: Well, I just have a suggesting for narrowing it down.

It goes back to what we talked about is a big part of our criteria for a screen is we picked out the cyclosiloxanes because of the very large volumes, and the fact that we had several studies, including the ones we did on computer in office equipment showing very large emissions and levels -- you know, and there are two studies of indoor environments in Germany and North America that report high levels indoors. That drove us, I think, to pull these up. So I would put the same test as the very first screen before you even give it to us as -- you know. If there are high levels or any studies showing measurements indoors or some level that would flag them, then don't go through all the other parts that we had to. Does that -- I think that might be a way to --

PANEL MEMBER BRADMAN: I think that's reasonable.

PANEL MEMBER McKONE: Right. Instead of doing like -- because there was a huge amount of work to do each of the chemicals here, but these were narrowed down through this process of looking at literature showing concentration measurements, indoors, high levels of production, high levels of use, changing patterns of use.

DR. ZEISE: Might I suggest at the next -- later on on the agenda, we have an update item. And we wanted to have some discussion around the agenda for the next meeting as part of that item. And so I think one of the issues will be well, what work should we do first, because we also would like to move to considering some priorities for sampling as well. So maybe we could revisit that issue about what to bring you information on next and see how you liked this and what you'd recommend us.

PANEL MEMBER BRADMAN: I'll do some homework too.

DR. LIPSETT: Could I also interject a brief comment in this regard. And that is that, going back to my presentation yesterday, recall that OEHHA has two staff who are dedicated to this program and they have a number of others who are contributing time to be able to respond and to staff the Panel. So I guess on the one hand, we want to be as responsive as we can to all the requests from the Panel for information. On the other hand, I would want to request the Panel when they're asking for

additional information that it be considered critical to your decision making and not just in the nice-to-know arena.

CHAIRPERSON MORENO: Thank you. One point or comment I have is that the group -- the topic -- I'm sorry, the class of chemicals that we just discussed, we had a process and we had both Panel member input and Program staff input to get to where we're at. And the next few steps that we're asking for within that classification, more information, would just be to -- additional information and I think that's probably -- Dr. Zeise, it's probably feasible to just get that additional information and bring it back, so we can complete the process and we make a decision on this class.

The recommendation from Dr. Bradman, I think, is new work. And I'd like to remind everyone that the process is going to be a little bit different, which means we may not be able to come back in the same timely manner that we did with the first group of chemicals that we're considering today. And so we should -- if we could come back at the end of the day and discuss that in the context of everything else we're going to be asking Program staff to do.

PANEL MEMBER BRADMAN: And I'll do some of my own homework on that. I just want to make sure we're

responsive to those comments.

PANEL MEMBER WILSON: In my mind, Michael, the challenge for me is -- and the need for some additional information is to be able to weigh away this class of substances against others that we're looking at, sort of vis-a-vis their public health risk. And so I appreciate that we're adding a burden to the staff in doing that, but it's important, I guess, in that regard.

So, I would -- I guess, I would make a proposal, if the Chair is amenable to it, that on the matter of cyclosiloxanes that the Panel defer decision on designation until staff have gathered and assessed additional information as specified by the Panel.

CHAIRPERSON MORENO: If it's appropriate, I'd like to go ahead and just make that as recommend -- general guidance to Program without making a proposal for a recommendation. Would that be all right?

Okay, with Panel members?

Okay. Thanks.

With that, I think we can move on.

OEHHA DIRECTOR DENTON: We did get an additional comment that came in during the Panel's discussion of the first recommendation. It was a comment from Dr. Amy Kyle of UC Berkeley. It was beyond the public comment period. And, although, we won't be discussing that or reading that

into the record, we will give it to the court reporter to be made part of the public record.

CHAIRPERSON MORENO: All right. Thanks.

All right, Panel members, it's 2:35, and what we had scheduled for the next topic after lunch was antimicrobials and synthetic hormones used in animal husbandry. That was originally scheduled to start at 1:45. So we are 50 minutes behind. I looked at how long it would take -- how much time we scheduled for this including public comment and final panel discussion recommendations and it was about an hour's worth of time. We were to start at 1:45 and we were to break at 2:45. So that's about an hour. If we were to start now and get through that topic on time, it would be 3:35. And we were scheduled to start -- have a break. And if we had a break at 3:45, we're looking at 4 o'clock before we get to the last item, which was update on pesticides, plasticizers and other flame retardants. And in that section, we were also going to talk about giving this panel an opportunity to discuss what we would like to see on the next agenda for the next meeting, because we heard, I think, yesterday some eagerness to start working towards prioritization.

Yes.

PANEL MEMBER SOLOMON: May I make a suggestion?

I asked Dr. Flessel a question earlier about the

laboratory capabilities on measuring antimicrobial resistance. And it appears that it could be useful for a conversation to occur with the Microbial Disease Lab here in the State of California, which I guess there hasn't yet been the time for that to happen to assess what exactly they're doing, what their capabilities are and what their interests might be in collaborating on a project like this, since we -- as we all know, the biomonitoring labs at the Program's disposal are not able to measure for bacterial resistance, which is the issue at hand in the next section.

So I would propose that in the interests of time, we perhaps skip over this agenda item and allow staff the opportunity to have that conversation and bring it back at the next meeting. Should I do that as a formal --

CHAIRPERSON MORENO: How do the other Panel members feel about that?

Dr. Denton.

OEHHA DIRECTOR DENTON: I'm wondering if there's anyone from the public that is here to testify on that item, that came specifically for that item?

It doesn't look like there is anyone. Okay.

CHAIRPERSON MORENO: Well, I understand that Dr. Rachel Roisman was going to give that presentation. And we really do want to get to this topic. But for now then,

I guess, at this point, we'll move on to the next topic, which was going to be the update on pesticides, plasticizers and from that point on we'll resume that as scheduled with that topic. And we will also include a discussion on the agenda for next -- and where we're at with that.

DR. ROISMAN: I just need to clarify one thing, because I'm not sure exactly what -- I didn't hear or didn't catch which laboratory you -- but I actually was in communication with one of the researchers in the CDPH Lab. And I'm not sure if that's the same lab that you're --

DR. FLESSEL: It's exactly the same lab and the person.

DR. ROISMAN: So I have the answer to that question, which is the punchline to the whole presentation.

PANEL MEMBER SOLOMON: Well, then --

MS. HOOVER: I mean, I would suggest that she go ahead and do her presentation. You can have an initial discussion. You don't have to make your decision. And that won't take long.

PANEL MEMBER SOLOMON: That sounds fine.

PANEL MEMBER WILSON: I would like to hear the presentation as well if we could then curtail discussion.

CHAIRPERSON MORENO: Counsel, can we abbreviate

that or do we still have to have public comment.

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: You still need to offer public comment, but if there's no one that's commenting, then there's not going to be a lot of time spent on that. You don't have to have your deliberations and stuff today. But it is kind of difficult sometimes to have a presentation and then try and remember it later without having to redo the whole thing the next time you consider it.

CHAIRPERSON MORENO: Okay. All right. Well, Dr. Roisman, thank you for brining that to our attention. So with that, back to the Panel, should we go ahead and go back and hear the topic of antimicrobials?

PANEL MEMBER SOLOMON: Sure.

CHAIRPERSON MORENO: All right. Well, then let's move forward and we'll try to keep the -- cut down the -- yes, go ahead, Dr. Roisman.

(Thereupon an overhead presentation was Presented as follows.)

DR. ROISMAN: How's that?

So I was going to speak on two topics that have some overlap, the use of antimicrobials in animal husbandry and the use of synthetic hormones in animal husbandry. I'll start with antimicrobials.

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DR. ROISMAN: So this first, which may be difficult to read, is a table showing a select group of classes of antimicrobials that are registered for use in livestock and poultry for the purposes of both treatment and prevention of infections as well as growth promotion. And you'll see that there are some that are used exclusively in animals. For instance, the ionophores which are on the top left corner there of the table. Although, more than half of the antimicrobials that are used for nontherapeutic purposes in animals are used to treat human disease.

In particular, you'll notice there are a couple in orange there, like virginiamycin, which are used to treat human disease and there are not very many alternatives. Virginiamycin is a close relative of an antibiotic that's kind of a last-ditch treatment in humans for methicillin resistant staph aureus infections, which have become increasingly and prevalent and serious in humans, and is also a last-ditch treatment for vancomycin resistant enterococcus, which is another potentially fatal infection in humans.

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DR. ROISMAN: So some of the challenges with a topic such as this is that there's no required reporting of the use of antimicrobial agents in food animals either

in terms of the quantities used or whether they're used for growth promotion or for treatment or prevention of infections. And you can see there's a wide range in terms of the actual numbers, the amount of antimicrobials used based on the animal that you're talking about and the specific antimicrobial.

Estimates vary widely, but there are estimates that between 40 and 70 percent of total antimicrobial use in the United States is for nontherapeutic purposes in livestock, meaning either to prevent disease or for the most part it's for growth promotion.

And exposure in humans occurs via two major mechanisms, either consumption of commercial meat products or via environmental exposure, usually through antimicrobials contained in animal waste.

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DR. ROISMAN: So in regards to the first point the consumption of commercial meat products. The FDA regulates the use of antimicrobials that can be used in animals. And then the USDA, through the Food Safety Inspection Service, which they have a national residue program, they do the actual testing. And they test, you know, a fairly small number of animals to see if they -- before slaughter to see if they have tissue levels of antimicrobials that are above tolerance levels that have

been set by the FDA. And as I mentioned, it's, you know, a fairly small sampling and very rare residue violations are detected.

In terms of environmental exposure, it's thought to be fairly significant. The antimicrobials are not well absorbed in animals. And a large percentage of them of the parent compound, in addition to any metabolites, are thought to be excreted. And the antimicrobial residue as well as resistant organisms, which I'll talk about more in a minute, tend to persist in animal waste.

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DR. ROISMAN: So the major health concern when you're talking about antimicrobials is not direct toxicity from antimicrobial residues in humans. And we found very little literature, you know if any, that was looking at antimicrobial residues in humans and making any connection to toxicity.

The major health concern is the development of drug resistant bacteria that are then transmitted from animals to humans via a variety of mechanisms, either through consumption of contaminated meat or animal to human transfer. This could either be from a farm animal to somebody who works on the farm or from a farm animal to another type of animal, an insect, a rodent. And all this has been demonstrated in studies. And then the resistant

bacteria is transmitted to humans at that point.

And then there's also pretty significant evidence of environmental transfer of resistant organisms. And there have been -- all of these mechanisms have been studied in a variety of ways, but they've been able to trace resistant organisms that end up in humans, either back to food crops or soil or, you know, to animals that have been exposed to antimicrobials, you know, on the farm somewhere. And these organisms tend to persist. They don't go away.

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DR. ROISMAN: In terms of the question of the efficacy of public health action. So antibiotic resistance is a large and growing public health problem. Losing effective treatments in humans is a significant concern. The development of multi-drug resistant bacteria can cause significant health problems in humans. And so monitoring antibiotic resistance in humans could be a tool both to reduce the non-essential antibiotic use that occurs in food animal production as well as in human clinical medicine.

Depending on the antimicrobial that you were talking about, it could be difficult to distinguish between these two, because there are a number of the antimicrobials that are used both in animals and in

humans. And you wouldn't really be able to tell, you know, an organism that was resistant to a particular antimicrobial that's used in animals and humans. It would be difficult to figure out where that resistant organism was coming from.

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DR. ROISMAN: So laboratory considerations are fairly significant. As I mentioned, really no -- I didn't find any data on levels of antimicrobial residues in humans. And this does not appear to be where, you know, people are focusing or the major scientific interest. What is of great scientific interest is the resistant organisms not on the antimicrobial residues. So don't think that detecting antimicrobial residues is likely to be fruitful. We're talking about very long-term, but low-dose exposure to the antimicrobials in animals. A lot of the compounds are water soluble.

And just an additional consideration to keep in mind would be that any biomonitoring of antimicrobials you'd have to take into account in the questionnaire what the -- you know, what the person's use of antimicrobials is, because the doses that an individual would be exposed to, because they are being treated for infection, would be much higher than what you would expect them to be exposed to from, you know, consumption of contaminated meat.

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DR. ROISMAN: So an alternative biomonitoring approach, that would really get at the question of interest, would be to biomonitor for microorganisms and then do further testing for resistance patterns. And this would be a completely different way of addressing this issue, but would really get at what everybody is interested in, which is whether -- or the extent to which resistant organisms develop in animals, because they're exposed to these antimicrobials and then the transmission of those resistant organisms from animals to humans.

And you could do this in one of two ways, either by looking at gastrointestinal flora in stool cultures or by looking at upper respiratory tract flora in nasal swab cultures.

However, the capacity for this type of testing is not something that the CDPH Lab or the DTSC Labs do. I think the laboratory that was in question earlier, I spoke with someone there that's not testing that, you know, that aspect of the California Department of Public Health labs does. This work would need to be done by collaboration with outside researchers who would need to have experience with this particular type of testing and presumably some funding for it as well.

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DR. ROISMAN: Now I was going to go straight into synthetic hormones, unless anybody wants to ask a question.

PANEL MEMBER SOLOMON: So I just want to make sure that I heard that right. So the California microbiology lab basically said that they won't do this or they can't do this. And they're not interested in developing anything like this?

DR. ROISMAN: Correct. The type of tests that they say -- they tend to -- they receive clinical -- they receive isolates from other places this sort of broad sampling of, you know, GI flora is a very different type of testing than what they're used to doing.

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DR. ROISMAN: So the next topic, which has some overlap, is synthetic hormones used in animal husbandry.

There are three synthetic hormones that are approved for use, again, regulated by the FDA in animals. Zeranol, which is a synthetic estrogen. It's administered by implantation of a pellet behind the ear that continuously releases the compound.

Of note, Zeranol shares metabolites with a mycotoxin that's produced by fungi that commonly contaminate corn. And this would be an issue later on when we talk about the laboratory issues.

The second synthetic hormone trenbolone acetate, TBA, which is a synthetic androgen, and that's also administered by this continuously releasing hormone pellet.

And the third synthetic hormone is melengestrol acetate or MGA, which is a synthetic progestin. And this is administered in cattle feed not by pellet. And it's also used -- in addition to its use for growth promotion, it's used for estrus synchronization and suppression.

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DR. ROISMAN: Well I'll note here that a number of these chemicals when they're administered to animals are often administered in combination either with each other or with natural hormones that are -- because natural hormones are also administered for growth promotion in animals.

In terms of exposure or potential exposure, again, there's no mandated volume of use reporting. What we do know is that the vast majority of cattle are implanted at least once in their lifetime with synthetic or combination of synthetic and natural hormones, and that many cattle receive more than one implant.

And, again, the primary exposure in humans is either via consumption of contaminated meat or from environmental exposure through animal waste.

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DR. ROISMAN: Consumption of commercial meat products, similar issues as with antimicrobials. The FDA regulates this and sets tolerance levels. The USDA, through the Food Safety Inspection Service and the National Residue Program, does this testing. And they test a fairly small number of samples and they detect a very small number of residue violations. And these all relate to what the FDA has decided as appropriate tolerance levels.

Environmental exposure, again, thought to be significant. There have been some estimates on the extent to which both synthetic and natural hormones are added to the environment above, kind of, base levels just because of their use for growth promotion in animals. And that's what the percentages up there represent.

And livestock farming is thought to be a major source of steroid hormones found in regional groundwater and external surface water.

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DR. ROISMAN: And the mechanism for this again is that these compounds end up in animal waste, which is manure could be applied as fertilizer or remains in feedlot retention ponds. And from there it may be retained in soil or transported to ground and surface

water.

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DR. ROISMAN: All these comments have just shown some evidence of persistence in the environment. Zeranol has been found in low concentrations in sewage discharge. TBA metabolites are stable in animal waste and have long half-lives in liquid manure. MGA, a similar story, were present for a long time after fertilization with solid dung and also has been found to be present after crops were cultivated on that soil.

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DR. ROISMAN: The health effects -- without going into great detail, and these are synthetic hormones. The health effects are thought to be -- you know, expected to be the same as those for the natural version. So Zeranol is a natural estrogen, the known cause of human breast and uterine cancer. TBA is a member of an -- is an anabolic steroid, which are listed as reproductive toxicants and listed under Proposition 65. MGA is a progesterone, which is also listed as known to cause cancer under Proposition 65.

And what's important is that, you know, it can be difficult to quantify the health effects from exposure to zeranol. But the concern really is for the additive effects of zeranol on top of other exposures to natural

estrogens. And that's difficult to quantify.

I should also add here that the additional complication with zeranol is that it does share these metabolites with a mycotoxin and so it's -- well, there have been -- really, the closest we came to finding studies that looked at the relationship between synthetic hormones in humans and adverse health effects was with zeranol. And there has been an association made between some of zeranol metabolites and precocious puberty in young girls.

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DR. ROISMAN: These compounds do have significance in terms of the ability to assess efficacy of public health actions. There's concern regarding their persistence and toxicity in the environment. Biomonitoring could be helpful in our efforts to keep synthetic hormones out of the food supply and out of the environment.

Again, it may be difficult to determine if the source of exposure is used in animal husbandry, in particular for zeranol where there's this, you know, additional exposure through the mycotoxin. And then with TBA since -- that it can be used as a -- you know, illegally it's an anabolic steroid that people can ingest that way. So just the presence of these synthetic

hormones in humans wouldn't necessarily tell you where they were coming from. Although, there are some lab methods to try to make those distinctions, but it could be complicated.

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DR. ROISMAN: And then finally lab considerations. So there's fairly limited experience with measuring these synthetic hormones in humans. There are sensitive methods that exist for detecting their use in animals. In part, this is because the use of these hormones in animals has been banned in the European community. And so they do have some sensitive methods that they've developed in order to help them figure out where there are violations. But there hasn't been, you know, nearly as much attention paid to measuring these low levels of these hormones in humans.

The equipment to do the type of testing is available in the lab, but development work would be necessary to establish and validate these methods.

CHAIRPERSON MORENO: Thank you, Dr. Roisman for that presentation.

If I could draw the Panel's attention to the fact that we have two Panel members that need to leave at 4, is that right?

And Dr. Denton is sharing with me that it will

probably take an hour to get through the second -- the next section has an hour scheduled. So if we were going to include -- of course, we want to include all Panel members in discussion of the agenda item for next meeting.

So if we got started on the next section at 3 o'clock, that gives us about five minutes right now to comment with regards to this presentation.

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: You want to ask one more time whether there's public comment?

CHAIRPERSON MORENO: I'm sorry?

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: You want to ask one more time about public comment?

CHAIRPERSON MORENO: Thank you. Is there anyone in the public who's here today that would like to comment on the presentation that was just provided to the Panel?

I don't see any.

So some quick comments from Panel members on the presentation or points of clarification.

PANEL MEMBER LUDERER: Well, one thing I just wanted to maybe propose is in the interests of us just having heard this excellent presentation, and then, you know, having a long time delay in between, we actually get to discuss it as a panel, whether it might be possible to do something like in the relatively near future of a teleconference that would include the whole panel that

would be open to the public. That might be one way to -- just sort of throwing it out here as a possibility.

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: Well, it's certainly not impossible to do a teleconference under the law, but it is difficult in terms of logistics, because you end up -- you can't have the members being in their offices, for example, or on a cell phone. Wherever the members are, it needs to be open to the public.

So what you end up having is like a group here and a group here and you're staffing both locations. And it logistically is very difficult.

PANEL MEMBER LUDERER: So you can't have the public call in?

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: No. I mean, you have to have -- well, the public could call in, but where -- you have to have a physical location where the public can be with the Panel members that are on the call. So that you'd have to open your office, for example, or you would have to go to another place where the public could be. It's not as simple as just doing, you know, here's the call-in number, anybody can talk.

DR. ZEISE: Lauren Zeise with OEHHA. One possibility to explore, and we could try to do this, would be to look at if you have locations on campus and Dr. Culver could join you there. And then we could look at a

location up here. So we can explore that as a possibility.

CHAIRPERSON MORENO: Okay. Any other comments by Panel members?

Okay. Well, thank you again.

We're going to go ahead then and move onto the next portion of the meeting, which is an update on pesticides, plasticizers, other flame retardants and Track II compounds. And who will be making that presentation?

Sara.

(Thereupon an overhead presentation was Presented as follows.)

MS. HOOVER: Okay. I'm just going to give you a brief update on the outstanding issues and then I'm going to do some points of discussion that have come up from yesterday and today just to remind you of what might be on future agendas.

So there are a couple of remaining potential designated chemicals left over from the June meeting and there was also, what we call, Track II. And that was a broader scoping of some high-use high-exposure chemicals that have some toxicity concerns.

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MS. HOOVER: Okay. So with regard to pesticides. There has been some initial scoping work done. And the

focus has been on looking for high-use chemicals. There's also some initial modeling work that Dr. McKone has been doing. We've also been looking into pet pesticides and other consumer pesticide products.

In terms of plasticizers, there's just a very initial investigation under way on emerging plasticizers.

In terms of flame retardants, as was mentioned, the topic was narrowed from flame retardants to the brominated and chlorinated flame retardants. So there's been some initial work on non-halogenated organophosphate flame retardants.

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MS. HOOVER: With regard to the, so-called, Track II chemicals, there were a couple of things identified in June. One was nitrosodimethylamine. As part of workgroup discussions, there was a suggestion that that be broadened to emerging drinking water contaminants.

And then cleaning agents was another area of investigation. Glycol ethers was the main focus of this. And, again, we've been looking into things that have a combination of high use and toxicity concerns.

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MS. HOOVER: So possible topics for the next SGP meeting agenda. And actually -- okay, so I think actually in making this slide, there was a typo. Let me go back

one.

It's not emerging drinking water contaminants. It's emerging drinking water disinfection byproducts is what that slide should actually read.

And then in terms of possible topics for the next SGP meeting agenda, there was some advice on study designs, which was discussed yesterday. There's some desire for more panel input on that. There's also consideration of additional potential designated chemicals. So we request panel input on those of greatest interest. As was just mentioned, we've been staffing the project beyond our two staff people and working a lot of nights and weekends. So we want to have some advice on some focus on what you'd like to hear about.

Cyclosiloxanes. Obviously, there's agreement that we want follow-up on that. There was brought up of other siloxanes. There's the pesticides, plasticizers. There's the emerging drinking water disinfection byproducts. The glycol ethers. And there's also a proposal from the public that I believe the Panel received and is also in the back of the room on triclocarban.

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MS. HOOVER: In terms of other possible topics, there's also -- there's been discussion of considering potential priority chemicals. So we'd like panel input on

what potential priority chemicals are of greatest interest to the Panel and also the type of documentation that you'd be interested in on the priority chemicals.

Now, here I just wanted to briefly remind you of the criteria for priority chemicals, which is directly from the legislation. This is just abbreviation of the criteria. The first is the degree of potential exposure. The second is the likelihood of a chemical being a carcinogen or toxicant. The third is the limit of laboratory detection. And then the next is that there can be other criteria that the Panel may agree to, so that's another possible meeting agenda topic.

And I just wanted to note as well that there will be some input on this topic from the State expert and public participation reports that are nearly complete and will be provided to you and released to the public soon.

Okay, so that's just sort of an initial outline for your discussion.

CHAIRPERSON MORENO: Thank you for that presentation. So what -- I didn't see that there was a handout --

MS. HOOVER: Sorry, Dr. Moreno. Let me just follow-up on one thing. We also realized in terms of what just happened with the antimicrobials and hormones, that should also be part of your discussion in terms of the

follow up that you want to do on that.

CHAIRPERSON MORENO: Thank you.

I didn't see a handout, so we'll probably be relying on your slides -- referring to your slides that are up here.

MS. HOOVER: Yeah.

CHAIRPERSON MORENO: Okay, thanks.

The two things that we're looking at, I think, considering is the list -- follow up on the chemicals that have been discussed and then chemicals that we haven't discussed yet. And the other is how we want -- in the next agenda -- oh, I'm sorry. For the next meeting, do we want to take some steps to set this panel up to start talking and having serious discussions about prioritizing? So those are the two things, I think, that we need to discuss at this time.

So where would the Panel like to start at this point?

PANEL MEMBER WILSON: I guess I have a clarifying question, Sara. Where did you go?

There you are.

That the substances listed here are of interest for potential designation. That's what --

MS. HOOVER: Yeah, this list is the additional potential designated.

PANEL MEMBER WILSON: Right. So that has to happen before we have a discussion of prioritization, right?

MS. HOOVER: Well, yeah, we talked about this before. So the law doesn't require you to prioritize all designated chemicals. So, you know, you have your pool of designated chemicals and you have possible priority chemicals that you can draw from the designated chemicals. So you could choose -- you know, you could actually choose that if, for example, if you had a broad consensus, that there was a priority chemical of great interest, you don't have to wait until you've gone through every possible designated chemical. We see it as an ongoing process where you could reconsider, add to the designated chemical list and also choose priority chemicals on an ongoing way. And that can also change, you know, over time. It's not a static list.

PANEL MEMBER McKONE: We were wondering just to review, now we pretty well eliminated all metals, except for vanadium, which we folded into the mixture. Just for our memory, I'm trying to member how we got rid of all the metals.

PANEL MEMBER SOLOMON: We didn't. All the metals are designated. Not all, but all the CDC metals.

PANEL MEMBER McKONE: That's right. But there

were no other -- other than vanadium was the only thing that we brought in that was new --

PANEL MEMBER SOLOMON: Right, that's not on the CDC list.

PANEL MEMBER McKONE: -- that's not on the CDC list. Yeah, that's what I meant. I mean, I remember discussing a lot of metals and they're all covered. Okay.

MS. HOOVER: Actually, that brought another topic to mind that actually came up on the State report and in some internal discussions. Nanosilver was raised as another issue as well. So, obviously, I should clarify that this is not a complete list of everything you might want to look at, but this is some of the things that have already been discussed and brought out.

PANEL MEMBER WILSON: Well, I guess, I would -- I guess if we're going to have a discussion about this sort of set of priorities -- is that what we're going to do at this point?

CHAIRPERSON MORENO: It's up to us, I think, at this point. We have to -- I would hope that -- this is the time for us to talk about maybe the process. As you recall, this panel had a discussion of the process we were going to take to designate chemicals. And now we may want to have a brief discussion of what process are we going to agree upon to pick the priority chemicals, right?

MS. HOOVER: (Ms. Hoover nods head.)

CHAIRPERSON MORENO: We have the criteria. What process do we want to take?

And I just want to remind the public that there will be an opportunity for public comment on this section of the agenda.

PANEL MEMBER WILSON: Well, I guess, I would encourage us -- I would like to have a discussion about the pesticide arena, given its importance in California and also in consumer products in California as a topic for designation, based on the criteria that Sara described.

So are we -- I'm just confused on the process here. If we are trying to identify from this list what we want to talk about next meeting.

MS. HOOVER: Yeah, I mean, basically, there's a lot of topics and clearly, you know, the agenda is going to be too jam packed. So we basically just want some advice on what you all consider to be the most important things to talk about at the next meeting.

PANEL MEMBER WILSON: Thank you.

Okay, given that, my sense from this list would be that we do need to try to address the pesticides and build on some of the work that we've done in that arena.

PANEL MEMBER McKONE: Just to clarify that. So I think I agree. You're suggesting we should make that high

on our agenda. I don't want to say priority.

(Laughter.)

PANEL MEMBER McKONE: That's the wrong word to say here. But make it high on our agenda that we discuss and make a decision about pesticides. And I would also add we may be ready to take some sort of action on siloxanes.

And I also think -- this is interesting. I think, you know, we're in different levels with different substances. But when you look at the diesel mixture and given time issues, we might want to see if we can start working in two realms. I mean, doing -- can we work in designating and starting to set priorities for ones that we've already been through? Because if we could start -- if we have enough information, because we asked for some new information on diesel, it's already been designated, but maybe we should get to work trying to go through diesel and even flame retardants to see if we can start setting priorities at our next meeting. So we'll do a little of both, a little bit of work in designation, a little bit of work in setting priorities. That's just sort of a suggestion.

CHAIRPERSON MORENO: Okay. So what I'm hearing is we've already agreed or we had some consensus earlier today that we were going to have follow-up discussion on

cyclosiloxanes. And there's a recommendation that we -- that staff prepare to present information on pesticides for the Panel for the next meeting, so the Panel may want to make a recommendation based on the information that's presented on pesticides, may make a recommendation to designate pesticides as well, is that correct, certain pesticides?

More discussion?

PANEL MEMBER SOLOMON: And then perhaps what we should do beyond that is have any staff energy focus towards helping to identify potential priority chemicals. And so beyond the cyclosiloxanes and the pesticides or -- well, I guess we might want to actually also bring to closure the animal husbandry chemicals that we started to discuss today.

So those, plus the pesticides, and then focused on priority chemicals. And to that end, I would think it might be helpful for various Panel members to identify or, you know, speak a little bit about what they're thinking about with regard to criteria for prioritization or specific chemicals on the CDC list or ones that we've already designated that might be potential priorities, so that then we can figure out what questions might need to be answered before the next meeting, so that we could set priority chemicals.

CHAIRPERSON MORENO: So Gina, if I heard -- oh, please. Go ahead.

PANEL MEMBER KAVANAUGH-LYNCH: I don't want us to forget that hanging out there is the possibility of adding more criteria to the list. And it seems to me we ought to figure out the criteria before we start actually choosing chemicals to discuss.

CHAIRPERSON MORENO: Okay. So there's -- what I'm hearing so far from the Panel is three classes of chemicals that we want to present -- we would like presented at the next meeting for the Panel to consider. And I'm also hearing that we would like to have some discussion on priorities.

Now, Dr. Solomon, did I understand that you said that you're interested in maybe allowing the Program staff to return with recommendations for priorities based on the criteria? Is that what you --

PANEL MEMBER SOLOMON: Well, what I was thinking is that in the next few minutes perhaps, Panel members could propose either criteria or individual chemicals or groups of chemicals that people would like to see brought before us for the next meeting for consideration for identification as priority chemicals.

And so, you know, anybody who has an opinion along those lines maybe should speak now, so that staff

will know where to put their energies and what to include in the notice for the next meeting.

DR. LIPSETT: Yeah, this is probably very redundant. But the criteria you do have in -- that are specified in the law are laid out behind Tab 3 on page 2. So you have these three criteria. And, Gina, I assume you're only referring to any additional criteria beyond those three, because the CDC reports for all of the CDC chemicals do have summaries of this information, right, that would really suffice -- well, in our opinion, would suffice to meet Criteria 1, 2 and 3.

PANEL MEMBER WILSON: Okay. Well, I guess I'll be clearer then on the pesticide side of things. That what I'm interested in is pesticides of high use that we had discussed previously in California that do not appear on the CDC list, and that we're -- those pesticides were identified earlier by the Panel and appeared in the first briefing materials provided to the Panel.

And then the second was the -- or would be the pesticide ingredients that appear in consumer products that have been identified by the Air Resources Board.

DR. ZEISE: Lauren Zeise with OEHHA.

So that, again, would be a follow-up piece that we would do in terms of possible designated chemicals. We would bring that to you in that way.

PANEL MEMBER WILSON: Exactly.

CHAIRPERSON MORENO: Dr. Culver?

Dr. Luderer.

PANEL MEMBER LUDERER: I would just -- in looking at these three criteria for the prioritization of chemicals and then kind of thinking about the discussion that we had yesterday having to do with the kind of sense of urgency of actually being able to start undertaking some analyses and having some results come out of this program, that maybe another criterion we might want to think about, at least sort of for the initial cut, would be, you know, the feasibility of what can the labs actually, you know, do, say, in the next year to two years, and looking at the presentations that Peter and Myrto made yesterday, you know, giving us a good overview of the kinds of things that might be possible, so that that really, at least for the first set of priority chemicals, I think that that kind of is important to take into consideration and might want to be one of our criteria.

PANEL MEMBER WILSON: The only caveat I would add to that is that it would be helpful for us to have perhaps, you know, an opinion on the relative -- you know, the relevance of AB 289 to this process. That perhaps with consultation with DTSC, who sounds like they're, at

this point, using that law, that that might affect that question.

DR. PETREAS: May I comment here?

I don't think it will help, because if you are to request AB 289 now, it would be about a year before they can send you the method and will take us more time to adapt and try out that method. So in terms of timing, Dr. Luderer specified that if you want something to be done now, it should be something that we can do already now.

DR. LIPSETT: Yeah. And even though there's this year that's specified in AB 289 for industry to produce methods to give to us, there's not much in the way of enforcement mechanisms. And if they decide not to do it or if it takes much longer than that, we can't really rely on that as something that would be incorporated into our process in the near future. It has yet to be tested even, I believe. So we don't even know how well that's going -- that mechanism is going to work.

PANEL MEMBER WILSON: I'm hearing a high degree of uncertainty about that.

(Laughter.)

PANEL MEMBER WILSON: Skepticism perhaps. Okay. I guess, though, it would be -- I'm, you know, interested in hearing how it is being used by DTSC. And if this -- if, in fact, they're running into this problem or not.

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: Sure. We can give you an update on that.

DR. PETREAS: We're not there yet. I mean, there's a mechanism that's started, but it's only the beginning.

CHAIRPERSON MORENO: Yes, we have two comments.

Go ahead.

PANEL MEMBER KAVANAUGH-LYNCH: So I wanted to suggest as a possible criteria to add in considering priority chemicals is specificity or uniqueness to California.

PANEL MEMBER SOLOMON: And I'd like to build on what Dr. Luderer said. I think that for identifying priority chemicals a lot is really going to hinge on the lab, and what's feasible within a reasonable timeframe. And I found the presentations yesterday extremely helpful. And what I would love to see is a somewhat maybe expanded version of that type of presentation that -- the presentation yesterday was assuming the full implementation of the Program, 1,000 samples, you know, the big rollout that we now know that we're probably not going to get anytime in the near future. And so maybe looking at a somewhat smaller sample -- no. Shaking your heads.

DR. FLESSEL: No, that wasn't my intention at

all. That was to explain to you what we could do in terms of analytic chemistry if we were not fully engaged in the sample management issue. If all of our limited resources, all the chemists who were in the laboratory now focused on doing sample analysis, where you brought the samples, you dropped them on our doorstep, we logged them in, tested them and gave you the results. So there was no sample management. That's what freed up the staff that we now have or would free up the staff we now have to do chemical analysis.

Otherwise, if we were going to do the study where we're out there involved in sample collection in the community study or any kind of alternative to the archived sample collaborations, right, we have to redirect staff towards those sample management activities and away from sample testing. So the 1,000 tests of urine, for example, is based on just doing the testing, not doing any of the sample management.

PANEL MEMBER SOLOMON: I understand that. Though, at one point yesterday, you did say that the reason -- the rationale for putting -- for calculating 1,000 was you were trying to figure out, you know, what it would take or how many -- for how many chemical groups you would be able to actually hit that to get the 2,000 samples --

DR. FLESSEL: There was no target to get the 2,000. We were just telling you what we thought we could do for those different panels. And it came out to be an order of magnitude of 1,000 per year.

PANEL MEMBER SOLOMON: That's different from what I heard.

But anyway, there were other -- so if there's no purpose to decreasing the sample size, though I would think that that might help a little bit with cost, then the -- I mean, the other thing would be to look at other chemical groups, because there were several that weren't listed.

So I would be interested in, now that the flame retardants are designated, taking a look at what -- you know, laying out a scenario whereby some subset of flame retardants could be, you know, included and what that would involve in terms of trade-offs, whether there would be any opportunity to do anything in addition to the flame retardants, if those were done or if that would be all and to sort of cost it out for us.

DR. FLESSEL: So if I understood --

PANEL MEMBER SOLOMON: And then there are some chemicals on the CDC list that similarly might be of interest. You looked at a scenario with the organophosphates, the pyrethroids are coming in to replace

the OPs for quite a few household uses, and so they would be of some interest. I'm curious what that would involve. And then there's other chemicals like perchlorate, which is of widespread concern in California, what's the feasibility of doing perchlorate? Could it be bundled with anything else or not? What would be, you know, the cost in trade-offs involved with doing that?

So those are the kinds of questions that I would think would interest me.

DR. FLESSEL: Can I see if I understand you?

You'd like us to broaden the scope of the chemicals that we might look at, say reduce the number of sample analyses and introduce more types of chemicals. Do pyrethroids in addition to the ones we suggested. Maybe do perchlorate in addition to the ones we've suggested. Doing fewer samples but more panels.

PANEL MEMBER SOLOMON: I'd be interested in that. And I'd also be interested in sort of -- I mean, you presented, for example, three categories, I think it was, you know, OPs, phthalates, BPA and --

DR. FLESSEL: PAHs.

PANEL MEMBER SOLOMON: -- PAHs, and said you could do two out of those three. And so, you know, if you add a few more bullets there, you know, flame retardants, perchlorate, pyrethroids, how many of that menu could you

do in what combos with that sort of limited pool of resources. And there might be others that, you know, would similarly fall -- you know, would be worth looking at too. Because I don't know the means you could do, you know, BP and phthalates and perchlorate and pyrethroids? Or if it would be -- you know, all the money would be blown on perchlorate. You know, those are the kinds of things that we're going to have to look at if we're trying to come up with a subset of priorities.

DR. FLESSEL: Okay.

PANEL MEMBER LUDERER: Kind of a related question, which we talked about this morning a little bit was whether the hydroxylated aromatic compounds and diesel exhaust could possibly be bundled with the PAHs that are part of the Panel that CDC measures. So that might be -- you know, that would also be useful information in terms of trying to chose priority chemicals.

CHAIRPERSON MORENO: If I may, just for a moment. So far, I just want to summarize periodically where we're at.

Getting back to the chemicals that the Panel wants to hear more information on next time. I still have a follow-up discussion on the hormones and antimicrobials that was presented today, pesticides not on the CDC list, and cyclosiloxanes, correct? Those are the three

classifications or chemicals that we're going to have further discussion next time.

In addition to that, there's been a couple of comments on suggestions for possible additional criteria that are consistent with statute under Section 105449(b). There's four criteria we can use. The fourth one being other criteria that the Panel may agree to. And I just reworded a couple of comments that were provided by Panel members.

One of those suggestions would be to add to the list of criteria something like, the limits of laboratory capacity. And keeping in mind the broad sense, it could be staffing. It could be resources, funding, equipment.

The other suggestion that I heard was something like -- one of the criteria being characteristics of chemical use unique to California. So those are the only two that I've heard. So is that -- so far that's what I'm hearing, is that correct, Panel members?

MS. HOOVER: Dr. Moreno, you might want to not limit it only to use, but you might want to say exposure. So characteristics of chemical use or exposure that are unique to California.

CHAIRPERSON MORENO: Okay.

PANEL MEMBER SOLOMON: Friendly amendment, could we say something like -- I hate to say "unique", because

that implies that it can't be found anywhere else in the world, but, you know, somewhat particular to California or -- because I think we're -- of special interest to California. I think we're -- we all know what we're trying to say, but I don't want to also get us into a box where we have to show that this is completely unique.

CHAIRPERSON MORENO: Thanks.

Dr. Zeise.

DR. ZEISE: Yeah. And so what I'm hearing is that at the meeting we will notice that there will be a discussion of criteria for -- the additional criteria that the Panel may agree to. And these are the criteria you want to explore at that meeting. So we'll have an agenda item on that before you move to considering priority chemicals.

CHAIRPERSON MORENO: Yes. And I guess if I could just quickly ask Dr. Zeise or counsel, we're not -- for today's agenda, we didn't tell the public that we're going to pick those additional criteria, so we can discuss it, but we're not going to pick criteria? Or can we go ahead and pick criteria today?

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: Yeah, you can have the discussion. I wouldn't make any decisions on priority, because it wasn't noticed.

CHAIRPERSON MORENO: No, not the priority. The

criteria to make the priority.

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: The criteria either, because that was not in the notice.

CHAIRPERSON MORENO: Okay. All right.

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: You can have the discussion but no decision.

CHAIRPERSON MORENO: All right, thank you.

DR. ZEISE: Just another point of clarification. So what I understood from Dr. Luderer's comments was that really the question is also a focus for laboratory feasibility is in the near-term. And so, of course, further out we'll have more capacity as we get more familiar with the analyses and so forth. So it is just the near-term analysis.

PANEL MEMBER BRADMAN: I have a brief question or comment. I hope this isn't a step backward. But CDC has changed a number of their analyses for NHANES, and they've expanded their list. I don't think actually they're planning to produce reports like the exposure reports that they've done in the past. But there's some compounds now, that they're doing, that aren't on this list. There's also some that they've developed methods for, for example, Homeland Security, but they're not necessarily doing for NHANES. So there's potentially other resources that CDC has. And I don't know if that would affect our designated

list.

DR. ZEISE: So my understanding is that the chemicals that are written up and part of their overall reporting would be included in the designated chemicals as designated chemicals. So at the next meeting we will bring those to you as well, so you have materials on them.

PANEL MEMBER BRADMAN: So not necessarily a method, but whether they have actually done measurements and produced some sort of publicly available document.

DR. ZEISE: That's my understanding. And maybe Carol can follow up with just confirming in terms of the legislation, either now or before the next meeting.

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: We'll have to look at what actually seems to be involved here, because it's certainly not just NHANES, but we'll have to see exactly what they meant.

DR. ZEISE: And they have a full discussion of the new reporting on their website.

PANEL MEMBER BRADMAN: Right.

DR. ZEISE: And I guess as part of the documentation for the priority chemicals, one possibility that was already brought up by Michael was the possibility of using for the CDC chemicals what the CDC has already written up on those chemicals. We do have an example, if you'd like us to put it up on the screen to get a feel for

what we're talking about.

I guess we have a question, if that would suffice for your discussion in considering priority chemicals?

You don't have to make a decision, but just some indication of, you know, how you would consider that information.

And maybe, as we get that up, you can continue on your discussion.

CHAIRPERSON MORENO: Okay, yes.

DR. ALEXEEFF: George Alexeeff. I had another thought. Actually, it's -- I think it's a continuation of Dr. Solomon's thought from yesterday, which we haven't come back to, and that was there were three possible scenarios for types of studies that could be done.

One was those related to the RFI. Another one was community studies. And a third one -- maybe it's part of community studies, but where the CDC would be able to do sampling and assist in the analysis. Now, maybe those three overlap but -- and as a result of that, Dr. Solomon was recommending that we look at priority chemicals that we would want CDC to do in that type of analysis.

So my thought was -- I was wondering whether it would be helpful at the next meeting to think about chemicals that would be useful, specifically to analyze in some specific kind of study that we might be trying to put

together.

PANEL MEMBER SOLOMON: If I may, just to follow up on that. Thanks for bringing that up, because I actually think that the criteria for the chemical selection for the study that CDC will do for us, which I understood to be pretty much the same as what we were calling the community study, is that -- I would think those criteria would be a little bit different. We're no longer constrained by our laboratory feasibility and capacity, but rather by CDC's. So some of the chemicals that we just designated today, for example, would not be things that we could ask them for. But we could, you know, pick from the entire CDC list and not worry about in -- I mean, I guess there's ten categories then at our disposal.

And so one of the -- and I think since that's a one-time thing, I'm not even sure that that counts as priority -- setting priority chemicals. I would argue that it would be advising staff -- I mean, the committee's role there is just to advise staff on some chemicals that might be of interest to include in a pilot study. And that the discussion around priority chemicals would be a little bit different. It would be sort of, you know, for going forward through the California program and the California labs.

And so I don't know exactly what the forum is for having the discussion about the pilot study and the chemicals that would be worth including for that. And also, whether we should wait till the next meeting or whether we should encourage staff to -- you know, my bias might be to -- you know, staff has, I think, heard a discussion from this panel yesterday. And maybe we could encourage them to move forward and put together a proposal for doing a community based study with CDC support and, you know, bring us a proposal at the next meeting.

CHAIRPERSON MORENO: Could I suggest that maybe one of the criteria be changed a little bit to say something like, "...the availability and limits of State and federal laboratory capacity." Because that CDC offer made -- it's one time, but there may be opportunities in the future. And as availability is there, staff -- the Panel can look at making certain chemical priorities.

DR. ZEISE: Again, it's not clear to me that you need to consider what we'd ask the CDC to do as priority chemicals. Another way of thinking about it is that it's providing you some information on feasibility and whether or not they would be important to sample in California.

So you may -- I think that, you know, there is another way of looking at what the CDC will do for us. It's not something they're going to do for us on an

ongoing basis. So it provides us an opportunity to explore what the best possibilities are.

CHAIRPERSON MORENO: Okay. I think Dr. Luderer, do you have a comment?

PANEL MEMBER LUDERER: I was really going to say basically what you just said that I think that we do want to think about what the chemicals would be that the CDC might measure, because those results might form the basis for deciding that we want to make one of those classes of chemicals a priority, subsequently for the lab here.

DR. LIPSETT: If I could just respond to Dr. Solomon's comment, too. We were planning to go forward with, you know, exploring different options, say, with UCSF and with CDC and we may not have like a full NIH proposal in February for the next meeting, but we will have something that we'll present to you for your input on.

OEHHA DIRECTOR DENTON: I'm trying to think what would be the most useful forum of providing the information on these designated chemicals for consideration as priority chemicals at the next meeting. There's quite a few chemicals, hundreds of chemicals. There's quite a few groups. I wonder -- we could sort of provide you this written information, which would be a lot of pages to sift through. But I'm also wondering if it

would be useful to develop kind of a matrix where we could take the criteria and at least have the first cut of sort of summarizing the criteria as applied to these designated chemicals.

DR. ZEISE: We could go ahead and produce something like that. In fact, DPH and OEHHA staff have started on such a matrix. So that would be feasible to do before the next meeting. And what we could do -- I think what we could do is provide the third report from CDC, which provides the kind of discussion up there you see for phthalates as background for the Panel, because it does go through and discuss the individual -- basically, the underlying information for different criteria. So we could produce that and get that to the Panel and it's available to the public on the website. So it's very easily accessible. We don't have to produce reams of paper to send out, and then we could also provide this matrix.

And, in addition, to get at those additional chemicals that aren't included in the third report, CDC has write-ups on those that they have on their website, so we could provide those as well. They're very clear, very understandable.

CHAIRPERSON MORENO: Dr. Bradman and then -- actually, you can go ahead. Asa.

PANEL MEMBER BRADMAN: Well, I just had a comment or wanted clarification. You talked about someone -- maybe it was you who talked about the laboratory feasibility as a criteria for setting priority chemicals.

And I would actually think we might want to set priority chemicals in some cases independent of laboratory feasibility, because that could set in motion a process that would define those as laboratory methods that need attention. It could trigger an AB 289 request that we think these things may be very important but we just can't do it. In other words, they are a priority and some attention needs to be done.

CHAIRPERSON MORENO: Thank you. If I could make -- get some clarification on the statute. These four criteria to designate the priority chemicals, they're not -- we don't have to meet each of those criteria, correct? We can consider them, but one chemical for priority doesn't necessarily have to meet each of those three criteria, does it?

Which means, if we add two more criteria to this, now we have five criteria. If we look at the chemical addresses, four of the five, the Panel can still recommend that chemical as a priority, right?

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: Yeah. I don't think that -- there's certainly no hierarchy or

requirement that all of these necessarily need to be met. I think they're considerations that you need to take a look at. But, you know, they're not kind of either/or questions anyway. And, once again, you know, these are recommendations and so you're giving advice and the Program still has to make the decisions in the long run.

CHAIRPERSON MORENO: All right. Thank you.

PANEL MEMBER WILSON: I guess in following up Asa's thought that I'm in agreement, to some extent, with that on the laboratory capacity question. And maybe rather than defining laboratory capacity as a criteria, it would be a consideration. And the suggestion that there be a matrix that allows us to sort of look at this set of substances based on some measures of these various criteria. That there be a measure of the laboratory capacity in there as one -- as a consideration, whether it's an analytical method, cost, time or whatever you think is the best method for us to understand to get a good sense of how we can best consider laboratory capacity. But I worry about setting it as an absolute criteria for the reasons that Asa describes.

CHAIRPERSON MORENO: If the Panel is in agreement that there needs to be some consideration of laboratory as a criteria, perhaps we could let the Program come back with a recommendation on how to word that criteria that

best suits the intent of the Panel and the laboratories.

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: Excuse me. This is Carol Monahan-Cummings. I just wanted to point out it's quarter of four. We haven't had the public comment and I don't know how the court reporter is doing, whether he's -- do you have to leave right at 4?

THE REPORTER: No, I am here for the duration.

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: But you probably need a break right at four or pretty close.

CHAIRPERSON MORENO: So maybe we could take a break at four unless we're finished at four. But we do need to take public comment. So, at this time, is there anyone currently here that has public -- a comment they want to share?

Okay. We do have one.

Mr. Baltz.

MR. BALTZ: Davis Baltz with Commonweal. I guess this will be our last chance for public comment today. So I do appreciate you making room at many points during the day.

I think we made some good progress today from my point of view, especially in the morning as we actually designated two sets -- two classes of chemicals.

From my point of view having watched this program evolve for quite awhile now, I am concerned that we can

continue to make progress. And I hope that when we come into our next meeting, we can actually have some proposals for prioritization. You know, I think we have a two-step process here. In addition to the CDC chemicals, then we're designating additional chemicals. And then after we designate them, then the next meeting or after that, we get to prioritization.

So coming back again to what we discussed yesterday about something of an imperative. Many of our points of view that the Program would do itself a favor by generating some data, we need to have some priority chemicals, so that we can direct the Program to go ahead and start doing some biomonitoring.

So this is just from my point of view, I hope that we can, at the end of the next meeting, actually have some lists of priority chemicals that we could actually start testing for.

Yesterday, I think there was pretty -- I don't know if I would say consensus, but there was a lot of agreement that the mother-child cohort that was proposed maybe using UCSF had a lot of merit to it to forward to CDC. So, obviously, we still need to figure out how to pay for collecting the samples and shipping them to CDC. But that would be something else that when we come into our next meeting, if we could sort of come to an agreement

that we did want to pursue that option, as opposed to some other community study or put two or three on the table with the intention to decide which one we want to pursue, I think that would be helpful.

Another idea that sort of came up in trying to raise the profile of the Program is have something like an open house for the lab. And I think that would be a good idea to sort of open the doors, show the new equipment that's been purchased, have some briefings and invite notable people in Sacramento and elsewhere to come and learn about the Program, so then we can build on that interest, not only among policy makers but also among the public.

In terms of, you know, the lab capacity, that's obviously going to have a big impact on which chemicals get tested. I heard yesterday that on the organic's side we could maybe do the perfluorinated or the POPs. I guess I'm thinking now of -- but we need to decide sometime soon if we're going to go the POPs' root or the perfluorinated root.

So this maybe something else to bring back to the next meeting, which classes of chemicals -- if we can't actually get to prioritize them, which ones are going to give us the most value.

And among finally the chemicals that are already

designated from being on the CDC list that I would personally like to see prioritized, I think that some discussion on Bisphenol A would be welcome. There's been a lot of developments just in the last couple of months. And, of course, we had a bill in Sacramento this year as well, but I think that should be something that might be worth talking about.

So I want to thank the Panel members for all of their work since the last meeting. I also want to thank all the staff who gave the wonderful presentations today and worked weekends and evenings. And I know that you were given a lot to do. And it's really appreciated by those of us who are watching the Program develop.

So thanks.

OEHHA DIRECTOR DENTON: We received one comment from Dr. Rebecca Sutton with the Environmental Working Group.

And Dr. Sutton says that, "Environmental Working Group supports the biomonitoring of widely used antimicrobial agents and pesticides, including triclosan, triclocarban and nanosilver, all mentioned briefly during this meeting. The Science Guidance Panel may need further information on these chemicals to designate or prioritize them. Triclosan and triclocarban are potent endocrine-disrupting compounds, and preliminary evidence

shows that nanosilver is significantly more toxic to mammalian cells than silver ions. We also strongly advocate biomonitoring for phthalates and BPA, as described by Dr. Peter Flessel yesterday.

"Thanks for the opportunity to comment."

CHAIRPERSON MORENO: All right. Panel members, we have ten minutes before we lose two of our Panel members. So at this time -- eight minutes -- if I could go over what -- I'm sorry, Dr. Solomon.

PANEL MEMBER SOLOMON: Yeah, sorry. I've been waiting awhile.

So, I guess my -- I have two things in regard to the public comment. I'm now increasingly worried that we'll paint ourselves into a corner if we say that priority chemicals have to be somehow particular to California, because it's clear that there are some ones that are of great concern to the commenters that are very -- have great concern to me as well and are very widespread and that are not necessarily particular to California.

So as long as we see these criteria as being ones where we don't have to meet them all. You know, Dr. Wilson already pointed out that there are some pros and cons to saying well, we have to make lab feasibility a hard and fast rule. So I think we'll be all right, as

long as it's clear that it's not and, and, and; and we have to meet everything down the checklist.

But my biggest concern is that, you know, designating chemicals is this Panel's easy job, because there's not really any limit on the number of things we can designate. You know, it's not, you know, setting quite as many wheels in motion to do so. And yet, today in a, you know, full-day meeting, we had, you know, five chemicals -- or groups of chemicals on the agenda and got through two of them. And so I'm a little concerned about the pace of our ability to do the really hard job, which is priority setting.

And what I'd like to request is that we not approach priority setting by going laboriously through each individual chemical or groups of chemicals, starting at the top of the CDC list all the way to the bottom or else we're not going to get there.

And so what I would propose is that this -- indeed, we use the CDC document that the staff produced this matrix. And that the staff come up with a set of recommendations or a short set of options for what we might want to set as priorities. And then, the Committee can then respond to those, can propose alternatives, and have the discussion around some options that are pretty well laid out and have -- you know, would be a manageable

size. Otherwise, we're going to end up kind of bogged down, I'm afraid.

CHAIRPERSON MORENO: If I could -- we have just a few more minutes. If I can summarize what the next meeting may look like, which would include that last recommendation. The next meeting could look like this, we have further presentation and discussion on those three classes of chemicals that the Panel this afternoon mentioned. And similar to the process that we had yesterday and today -- I mean today, the Panel may make recommendations for designating chemicals.

That could be followed with a discussion of additional criteria and recommendations or the creation of additional criteria by the Panel for recommending priority chemicals. And that could be followed with a presentation of designated chemicals, the criteria for recommending priorities and a presentation by Program staff to get the conversation going on what those priority chemicals could be, focusing on those priority chemicals using the criteria that have been established.

So that's my -- that's how I'm possibly seeing the next meeting going. And that would allow us time to finish some discussions we had and make a determination -- someone can make a recommendation from the Panel to designate some chemicals early in that meeting and then

move into applying the criteria with work that the Program staff have already done and move us into discussions of the most likely chemicals that will be priorities.

PANEL MEMBER SOLOMON: Sorry to add one more thing. I fully agree with the Chair's summary. I was just -- I just wanted to hark back again to what Dr. McKone said earlier about wanting to test for tomorrow's chemicals not yesterday's chemicals.

And I've heard that sentiment from a number of other Panel members. And I'm not sure it quite -- maybe, it rises to the level of being something that we should propose as one of our criteria. But at a minimum, I think it's worth reminding ourselves of it and having staff keep that in mind as they come up with a list of potential chemicals to designate as priority chemicals.

PANEL MEMBER WILSON: I would agree with that. And I don't know if you included the presentation of a matrix in that. And perhaps it was subsumed in your agenda there. One thing I would like to add also is the opinion from OEHHA counsel on AB 289.

CHAIRPERSON MORENO: Could we have that presentation? Well, I guess Program staff can make a recommendation on how to set up that agenda, but early enough so that as decisions are being made, we have that information available to us.

Thanks.

PANEL MEMBER KAVANAUGH-LYNCH: Two things. Did you -- one is, did you want to mention the community study and the presentation in that list?

CHAIRPERSON MORENO: No, I didn't. We're going to have an update there too.

PANEL MEMBER KAVANAUGH-LYNCH: And the second thing that I just went back and looked at and noticed is on the presentation Sara gave this morning that started today's agenda, her third slide, where she has -- we have, you know, the CDC chemicals, then the designated chemicals and then the priority chemicals. And then after priority chemicals is feasibility, which then leads to which chemicals are actually biomonitored.

So I just wanted to point out, as we're talking about criteria, that feasibility is actually in the model already after we determine priorities. So we can -- it frees us up to determine priorities, sort of, free of feasibility. And then let feasibility play a role in deciding what actually gets biomonitored.

CHAIRPERSON MORENO: Okay. Can I -- I'm sorry -- come back to last comments from our two Panel members that need to leave? I want to make sure you guys had an opportunity.

All right.

Joan.

OEHHA DIRECTOR DENTON: I'm just back to Gina's comment earlier. I think, again, we have to kind of keep in mind that one of the purposes of the Program is to be able to reflect on the success of the regulatory programs, the environmental contaminant regulatory program. That's one of the purposes of the Biomonitoring Program.

So somehow we have to kind of dovetail the old with the new somehow, because that is a key element of the Program. Something to keep in mind along with all these other things.

PANEL MEMBER SOLOMON: I totally agree. What I was thinking about more, you know, from personal perspective, I think maybe PCBs many of the organochlorine pesticides sort of going far enough back, that I'm not as sure that they would be as high a priority, at least for me.

Some of the chemicals in recent use, where we're very, very interested in knowing whether their, you know, use is indeed diminishing, whether exposure is indeed diminishing, specifically, as a result of regulations or actions here in California. Those, I think, would be very important.

CHAIRPERSON MORENO: I think perhaps that could be one of the considerations should the Panel adopt a

criteria that includes characteristics of the chemical use and exposure. That would apply -- we could also look at past, current or future use.

And there's only two criteria so far that I've heard from Panel members. One was that characteristics that are unique -- well, not unique, but Program staff will come up with some recommended language. But basically chemicals unique to California and chemicals that take into consideration the capacity of the laboratories.

DR. ROISMAN: If I could ask one question before we lose whichever Panel members we're about to lose. But it would be helpful if we could get some direction on the antimicrobials and animal husbandry, otherwise -- because we're not going to be able to discuss this with Panel members after this meeting until the next one. And I'd like us to be able to go forward to some extent on those topics.

CHAIRPERSON MORENO: My understanding was --

DR. ZEISE: What more would you like to see?

CHAIRPERSON MORENO: What more?

Okay.

Dr. Luderer and Dr. Culver have to leave now.

The question from Dr. Zeise is do we have any other requests of the Program staff that they could bring

with them to the next meeting before we have the discussion that we postponed on antimicrobials?

Anything else?

OEHHA DIRECTOR DENTON: When was your thought about the next meeting? What's the timing for the next meeting? That's quite a few things that we need to put together and so forth.

DR. ZEISE: Yeah, I think we need to put our heads together with all of our staff, because as you've heard from the labs, timing is very critical. So before we make any commitments, if we could talk among ourselves. I mean, I guess February would probably be about the earliest.

PANEL MEMBER WILSON: Well, I think Dr. Luderer was working on the antimicrobials, right, but she just stepped out. I mean in responding to your question, Dr. Roisman, in terms of Panel input for you. I think she was working on that, right? Does anybody remember?

PANEL MEMBER SOLOMON: Yeah, she was the lead on those. And I don't believe that -- I mean, I don't have any outstanding questions and would feel comfortable, you know, making a recommendation on each -- you know, not necessarily the same recommendation for each category, but, you know, making recommendations one way or the other on those. It was just the fact that we ran out of time.

So I wouldn't request anything else from staff at this point.

OEHHA DIRECTOR DENTON: And I think the thought was there wasn't time to complete the item today, so the Panel heard the information. The Panel heard the staff presentation. But the time for the Panel discussion, we just ran out of time, which would mean that we would -- there would be another item for the next agenda.

PANEL MEMBER SOLOMON: I hope we don't have to redo the presentation at the next meeting.

CHAIRPERSON MORENO: Does that give you what you need, Dr. Roisman?

DR. ROISMAN: Sure.

OEHHA DIRECTOR DENTON: Maybe I could mention that we got another comment sort of out of the -- on the synthetic hormones that I'll put into the record, but won't read for the purposes of today from Dr. Miglena Wilbur.

CHAIRPERSON MORENO: All right. At this point, I believe that's it. Are there any other further comments by Panel members?

I don't see anything -- I'm sorry?

MS. HOOVER: We need to take a break for the court reporter at least briefly before we close the meeting.

Are you okay to go?

THE COURT REPORTER: I am fine. Thank you.

MS. HOOVER: We just had to double check. It's supposed to be every two hours.

CHAIRPERSON MORENO: So at this point, I'd like to introduce, Dr. George Alexeeff, who will give a summary of today's events.

Thanks.

DR. ALEXEEFF: Okay. This is George Alexeeff.

Well, yesterday we spoke primarily about smaller scale biomonitoring studies, in light of the current funding situation. And a couple of the issues raised were to focus these studies on community studies that were meaningful to larger populations, possibly a maternal child type of design. And to also focus on descriptive information that one could obtain.

Today, we discussed an overview of the designated chemicals and the role of the SGP in identifying them. And we followed up on potentially designated chemicals that were identified at the June meeting. Documents were produced on six of these chemicals or six of these chemicals or groups of chemicals.

Regarding diesel exhaust and vanadium, there was discussion about the difficulty in measurement of it, and that possibly some methods could be produced in the

future. And as a result of the discussion of diesel exhaust and vanadium, the Panel recommended unanimously that diesel exhaust be added to the list of designated chemicals of the Biomonitoring Program.

We discussed brominated and chlorinated flame retardants. And it appeared that there were a number of methods available for these compounds. And the Panel unanimously recommended that brominated and chlorinated organic compounds used as flame retardants be included -- used as flame retardants, including but not limited to those specifically listed on page 2 and 32 of the staff report, be added to the list of designated chemicals for the Biomonitoring Program.

We also discussed siloxanes and some additional materials were being requested from both staff and the public regarding this compound to be discussed at a later meeting. There was a recommendation to postpone, but it was a split vote, but resulted in us waiting until the next meeting until we get some additional materials.

There was a presentation about antimicrobials used in animal husbandry, as well as synthetic hormones used in animal husbandry. We weren't able to complete the item and will continue with the item at the next meeting.

We discussed the next meeting, and what might be on the agenda. There will be a follow-up of the items

that we didn't complete at this meeting, the cyclosiloxanes and the animal husbandry chemicals.

And also, I believe there was a request for us to look at additional pesticides that are in high use, but not on the CDC list. Finally, there would be a discussion of the criteria for recommending priorities, including discussion of potential priority chemicals. And an update on the smaller scale biomonitoring studies.

Oh, also an update on the -- well, staff update on the opinion of 289, AB 289.

That concludes my summary.

CHAIRPERSON MORENO: Okay. I don't think there's any other business. I think we're done. So we'll adjourn this meeting and we'll hear from staff in the near future as far as plans for the next Biomonitoring Panel meeting, right?

Thank you very much.

Before we leave I and Dr. Denton would like to thank Dr. Peter Flessel for, again -- when it comes to thanks, I'm a man of few words. So actually I say thank you and I mean it sincerely.

Dr. Denton, do you have anything else to add?

OEHHA DIRECTOR DENTON: That's pretty much what I wanted to do. Thank you, Peter. We wish you good luck in your retirement. We will miss you at these meetings. And

we're not sure you'll miss us, but we know we'll miss you.

(Laughter.)

DR. FLESSEL: No, the feeling is absolutely mutual. And thank you all very much.

(Thereupon the California Environmental Contaminant Biomonitoring Program Scientific Guidance Panel meeting adjourned at 4:09 p.m.)

CERTIFICATE OF REPORTER

I, JAMES F. PETERS, a Certified Shorthand Reporter of the State of California, and Registered Professional Reporter, do hereby certify:

That I am a disinterested person herein; that the foregoing California Environmental Contamination Biomonitoring Program Scientific Guidance Panel meeting was reported in shorthand by me, James F. Peters, a Certified Shorthand Reporter of the State of California, and thereafter transcribed into typewriting.

I further certify that I am not of counsel or attorney for any of the parties to said meeting nor in any way interested in the outcome of said meeting.

IN WITNESS WHEREOF, I have hereunto set my hand this 15th day of December 2008.

JAMES F. PETERS, CSR, RPR
Certified Shorthand Reporter
License No. 10063